No. 17-3030

In the United States Court of Appeals for the Seventh Circuit

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, Deceased,

Plaintiff-Appellee,

v.

GLAXOSMITHKLINE LLC, Formerly Known as SMITHKLINE BEECHAM CORPORATION,

Defendant-Appellant.

On Appeal from the United States District Court for the Northern District of Illinois
No. 12-cv-6403 (Hon. William T. Hart)

BRIEF OF APPELLANT

Andrew T. Bayman
Todd P. Davis
Heather M. Howard
KING & SPALDING LLP
1180 Peachtree Street, N.E.
Atlanta, GA 30309

Alan S. Gilbert
DENTONS US LLP
232 S. Wacker Drive, Suite 5900
Chicago, IL 60606

Lisa S. Blatt
Counsel of Record
Elisabeth S. Theodore
William C. Perdue
Stephen K. Wirth
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., N.W.
Washington, DC 20001
(202) 942-5000
lisa.blatt@apks.com

Counsel for GlaxoSmithKline LLC

January 22, 2018

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 17-3030

Short Caption: Wendy Dolin v. GlaxoSmithKline LLC

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statement be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

[ ] PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P 26.1 by completing item #3):

GlaxoSmithKline LLC

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP; Dentons US LLP; King & Spalding LLP; Phillips Lytle LLP;

Troutman Sanders LLP

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

GlaxoSmithKline LLC is an LLC whose sole member is GlaxoSmithKline Holdings (Americas) Inc.

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

GlaxoSmithKline LLC is an indirect wholly-owned subsidiary of GlaxoSmithKline plc, a publicly traded company organized under the laws of England.

Attorney's Signature: S/ Lisa S. Blatt Date: January 22, 2018

Attorney's Printed Name: Lisa S. Blatt

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** ____

Address: 601 Massachusetts Ave. NW

Washington, DC 20001

Phone Number: (202) 942-5842 Fax Number: (202) 942-5999

Email: lisa.blatt@apks.com

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Attorney's Signature: s/ Alan S. Gilbert Date: January 23, 2018

Attorney's Printed Name: Alan S. Gilbert

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ____ **No** X

Address: 233 South Wacker Drive, Suite 5900
Chicago, IL 60606

Phone Number: (312) 876-7410 Fax Number: (312) 876-7934

E-Mail Address: alan.gilbert@dentons.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

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ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

GlaxoSmithKline LLC is an indirect wholly-owned subsidiary of GlaxoSmithKline PLC, a publicly traded*

Attorney's Signature: s/ *Andrew T. Bayman* Date: November 15, 2017

Attorney's Printed Name: Andrew T. Bayman

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** _____ **No** X

Address: 1180 Peachtree Street, N.E.
Atlanta, GA 30309

Phone Number: (404) 572-3583 Fax Number: (404) 572-5100

E-Mail Address: abayman@kslaw.com

*company organized under the laws of England.

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JURISDICTIONAL STATEMENT

The district court possessed subject-matter jurisdiction under 28 U.S.C. § 1332(a)(1). Plaintiff-appellee Wendy Dolin is a citizen of Illinois, as was the decedent, Stewart Dolin. Defendant-appellant GlaxoSmithKline (GSK) is a limited liability company organized under Delaware law. GSK's sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its principal place of business in Wilmington, Delaware. The amount in controversy exceeds $75,000: The jury returned a $3,000,000 verdict.

GSK timely moved for a new trial on May 25, 2017. The district court denied that motion and entered final judgment on September 14, 2017. On September 26, 2017, GSK timely filed a notice of appeal and a renewed motion for judgment as a matter of law, which the district court denied on September 28, 2017. GSK filed an amended notice of appeal on October 2, 2017. This Court has jurisdiction under 28 U.S.C. § 1291.

ISSUES PRESENTED

1. Whether GSK is entitled to judgment as a matter of law because it did not produce, market, or sell the product plaintiff alleges caused decedent's death.

2. Whether plaintiff's claims are preempted under *Wyeth v. Levine*, 555 U.S. 555 (2009), because it was impossible under federal law for GSK unilaterally to provide the warning plaintiff contends state law requires.

3. Whether GSK is entitled to judgment as a matter of law because the evidence did not show that (a) paroxetine causes suicide in adults older than 24,

(b) GSK had a duty to warn decedent's doctor, or (c) decedent's doctor would have declined to prescribe paroxetine had the warning been different.

INTRODUCTION

Between 1992 and 2014, GSK manufactured and marketed Paxil IR, a brand-name prescription medication approved to treat major depressive disorder and other psychiatric disorders. Paxil's active ingredient is paroxetine hydrochloride (paroxetine), a selective serotonin reuptake inhibitor (SSRI). Paroxetine and other SSRIs have improved the lives of hundreds of millions of people suffering from anxiety and depression. FDA has approved Paxil as safe and effective.

In 2010, Stewart Dolin committed suicide at age 57, following a decades-long battle with anxiety and depression and while struggling under intense pressure at work. At the time of his death, Dolin was not taking Paxil, nor had he ever; rather, he was taking a generic version of paroxetine manufactured and marketed by Mylan Pharmaceuticals Inc., a GSK competitor. GSK did not manufacture, market, distribute, sell, or profit from the drug Dolin ingested. Nonetheless, Dolin's wife, Wendy Dolin, sued GSK, claiming that Illinois would recognize a novel legal theory known as "innovator liability." She claimed that, because GSK developed Paxil's labeling and federal law requires generic paroxetine's labeling to match Paxil's, GSK was responsible for failing to warn Dolin's doctor about a risk of suicidal thoughts and behavior allegedly presented by Mylan's drug. The district court adopted that theory, and the jury awarded a verdict against GSK.

Dolin's suicide is tragic, but GSK never belonged in a courtroom defending against claims for injuries allegedly caused by a product it did not make or market. Courts nationwide have overwhelmingly rejected innovator liability as incompatible with basic tort principles. The theory would deter innovation, turning companies that develop life-saving medications into insurers of their entire industry. As the Sixth Circuit has now concluded, innovator liability is irreconcilable with Illinois law. The theory also is preempted under federal law, as it would destroy the careful balance between competition and innovation enshrined in the Hatch-Waxman Act.

Nor may GSK be liable for failing to give a warning FDA rejected. Under *Wyeth v. Levine*, 555 U.S. 555 (2009), federal law preempts a failure-to-warn claim based on a warning FDA *would* have refused. A fortiori, there is preemption here, because FDA *already* rejected the warning plaintiff seeks. Based on the same data plaintiff now cites, GSK asked FDA *four times* for approval to warn about a possible association between Paxil and suicidality in adults older than 24. FDA rejected each of those requests and ordered GSK to remove from its labeling the same warning plaintiff faults GSK for not providing. If there were ever a case for preemption under *Wyeth*, this is it.

Plaintiff also presented insufficient evidence of multiple elements of her claim. FDA rejected the warning plaintiff claims state law requires precisely because there is no reliable evidence that paroxetine is associated with suicide past age 24, much less causes it. What the evidence at trial *did* establish was that Dolin's physician prescribed paroxetine despite knowing the very information

plaintiff claims GSK should have warned about. The physician even conveyed that information to Dolin and plaintiff.

In short, the judgment below is based on a product GSK did not make, a warning FDA rejected, and a purported risk Dolin's doctor knew of and warned about. This Court should reverse.

STATEMENT OF THE CASE

A. Regulatory Background

The Food, Drug and Cosmetic Act bars manufacturers from marketing new brand-name drugs unless FDA approves a "new drug application" (NDA). 21 U.S.C. § 355(a). An NDA must show that the drug is safe and effective, § 355(d), which entails "an extensive series of safety and effectiveness trials." *Guilbeau v. Pfizer Inc.*, __ F.3d __, 2018 WL 476343, at *2 (7th Cir. Jan. 19, 2018). Generic manufacturers, however, can avoid those costs. Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as Hatch-Waxman, generic manufacturers may file abbreviated NDAs, which need only demonstrate that the generic drug is biologically equivalent to a previously approved brand drug. *Id.* In exchange, Hatch-Waxman provides brand manufacturers with enhanced patent and regulatory exclusivities. *E.g.*, 21 U.S.C. §§ 156, 355(c)(3)(E)(ii)-(iv).

Manufacturers generally may not change their drugs' labeling without FDA's prior approval. 21 C.F.R. § 314.70(b)(2)(v)(A). In narrow circumstances, however, FDA's "Changes Being Effected" (CBE) regulation permits brand manufacturers to change labeling unilaterally "[t]o add or strengthen a … warning," but only to

reflect "newly acquired information" that was "not previously submitted to [FDA]." §§ 314.70(c)(6)(iii), 314.3. FDA retains authority to later reject such a change. § 314.70(c)(7). Generic manufacturers, for their part, must match their labeling to "the corresponding brand-name labels." *Wagner v. Teva Pharm. USA, Inc.*, 840 F.3d 355, 358 (7th Cir. 2016) (quotation marks omitted).

Manufacturers and FDA alike must keep drug warnings up to date. For drugs like Paxil approved before 2001, manufacturers must seek approval "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.80(e); *see* § 201.57(c)(6)(i) (similar for newer drugs). Likewise, if FDA "becomes aware of new safety information that … should be included in the [drug's] labeling," it must "promptly notify" the manufacturer and "initiate discussions to reach agreement on whether the labeling for the drug should be modified." 21 U.S.C. § 355(o)(4)(A), (C). Additional warnings are not always beneficial; "overwarnings … can render the warnings useless and discourage use of beneficial medications." *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1102 (10th Cir. 2017).

B. Paxil and Generic Paroxetine

GSK manufactured and marketed Paxil in the United States from 1992 to 2014, when GSK sold Paxil's NDA to a competitor, Apotex. R.87 ¶5; R.376 at 2 n.1. GSK no longer manufactures, markets, or profits from any sale of Paxil in the United States.

Generic paroxetine entered the U.S. market in 2003; Mylan began selling it in 2008. GSK had no control over Mylan's development, manufacturing, distribution, or marketing. R.87 ¶11. Nor did GSK profit from Mylan's paroxetine sales. *Id.* ¶14. Quite the contrary: State drug-substitution laws permit or require pharmacists to dispense generic paroxetine in place of Paxil unless the prescribing physician directs otherwise. *New York ex rel. Schneiderman v. Actavis plc*, 787 F.3d 638, 644-45 (2d Cir. 2015); *e.g.*, 225 Ill. Comp. Stat. 85/25. Within a year of generic entry, Paxil's profits fell by 91%. By 2010, when Dolin took paroxetine, Paxil retained only 1% of the market.

C. FDA Determinations that Paxil Is Not Associated with Suicidality Past Age 24

For nearly three decades, FDA has rejected any association between any SSRI, including Paxil, and suicidality past age 24. In 1991, an independent FDA advisory committee found "no credible evidence" that the only SSRI then available increased suicidality for any age group. R.308-2 at 71; *see* R.308-13 at 75, 80. FDA rejected that association again when it approved the Paxil NDA in 1992, R.308-2 at 97-98, and yet again when it approved Paxil for a new indication in 1995, *id.* at 125-38.

In the early 2000s, FDA found "no significant difference in suicide rates between [SSRIs] and placebo," R.308-4 at 89, "no[] … increased risk of completed suicide associated with" SSRIs, R.308-6 at 16, and "no evidence that Paxil is associated with an increased risk of suicidal thinking in adults," R.308-5 at 118. In 2004, however, FDA concluded that SSRIs pose an increased suicidality risk for

pediatric patients, and mandated a warning to that effect. R.308-7 at 13-19. Paxil's FDA-approved labeling stated that "[i]t is … unknown whether the suicidality risk extends to adults." R.308-8 at 146. Nevertheless, the labeling warned that patients of *all* ages should be monitored for clinical worsening, suicidality, and associated symptoms. *Id.* at 146-47.

Beginning in 2004, FDA asked SSRI manufacturers to provide clinical data to enable FDA to assess whether antidepressants increase the risk of suicidality in adults. R.589-14 at 7. FDA "request[ed] information from placebo controlled trials only," and directed manufacturers "not [to] submit" data from other studies. *Id.* at 50. FDA actively participated in determining which studies to include, and suicidality events in the data were categorized using a new methodology developed at Columbia University. *Id.* at 8, 12.

GSK also conducted its own re-analysis of Paxil adult-suicidality data using the new classification methodology. R.589-21 at 1-3. As summarized in a briefing document submitted to FDA in April 2006, "[o]n the primary endpoint of *definitive suicidal behavior or ideation*," GSK found "no statistically significant difference" between adults treated with paroxetine compared to placebo. *Id.* at 11. But when examining a secondary endpoint—suicide attempts alone—in a subset of clinical trials, GSK did find "evidence of an increase … with paroxetine compared to placebo." *Id.* GSK urged caution in interpreting the data, however, because the absolute number and incidence of events were very small. *Id.*

GSK did not believe this re-analysis established a "causal relationship" between paroxetine and suicidality in adults. *Id.* at 4. Nonetheless, on April 27, 2006, out of an abundance of caution, GSK changed Paxil's labeling under the CBE regulation. R.589-22 at 1. GSK deleted the statement, "It is … unknown whether the suicidality risk extends to adults," *cf.* R.589-5 at 12, warned that "[y]oung adults [ages 18-24] … may be at increased risk for suicidal behavior," *id.*, and stated:

> *In adults with MDD* [*major depressive disorder*] *(all ages), there was a statistically significant increase in the frequency of suicidal behavior* in patients treated with paroxetine compared with placebo (11/3,455 [0.32%] versus 1/1,978 [0.05%]); all of the events were suicide attempts. However, the majority of these attempts for paroxetine (8 of 11) were in younger adults aged 18-30 years. *These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24*.

Id. (emphases added). In May 2006, GSK sent a letter to doctors nationwide, including Dolin's prescriber, attaching Paxil's new labeling and explaining the "important changes to the Clinical Worsening and Suicide Risk subsection of the Warnings section." R.589-4 at 1, 3-14.

In December 2006, FDA released its extensive meta-analysis of 372 placebo-controlled clinical trials involving nearly 100,000 adult patients. R.589-14 at 8. FDA found "an elevated risk for suicidality and suicidal behavior among adults younger than 25," but concluded that the "net effect appears to be neutral on suicidal behavior but possibly protective for suicidality for adults between the ages of 25 and 64 and to reduce the risk of both suicidality and suicidal behavior in subjects aged 65 years and older." *Id.* at 44. FDA held a public hearing on its analysis, where two

of plaintiff's experts unsuccessfully criticized FDA's approach. R.308-10 at 183-87, 206-07.

Based on its meta-analysis, FDA on May 1, 2007 directed GSK and other SSRI manufacturers to revise their labeling. FDA instructed GSK "to make revisions to [the Paxil] labeling … so as to ensure standardized labeling pertaining to adult suicidality." R.589-23 at 1. FDA ordered all SSRI labeling to warn of a suicidality risk in persons *24 or under* (as GSK had done since 2006). FDA also ordered all SSRI labeling, including Paxil's, to state:

- "Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older."
- "Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide."
- "There were suicides in the adult trials but the number was not sufficient to reach any conclusion about drug effect on suicide."
- "Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior."

R.589-23 at 2-3. FDA required all SSRI labeling to include this language "verbatim." R.589-24 at 1.

In response to FDA's letter, GSK asked FDA *four times* for approval to retain a Paxil-specific adult-suicidality warning in addition to the standardized warning for all SSRIs. FDA rejected each request.

First, on May 7, 2007, GSK asked to retain the warning GSK had added via the April 2006 CBE supplement. R.589-25 at 1. FDA declined, directing GSK to "replace the previous warning section with the new language [FDA] provided." *Id.*

Second, on May 11, 2007, GSK sent FDA a letter "proposing to maintain the Paxil specific language within the new class labeling." R.589-26 at 1. GSK urged that "the Paxil specific paragraph … would complement the class labeling" and "could help physicians." R.589-27 at 1. FDA deferred ruling on that request, advising GSK to submit it as a separate CBE supplement. R.589-28 at 1.

Third, on May 23, 2007, as directed, GSK submitted a second CBE supplement, again proposing that "the paroxetine specific language [be] maintained." R.589-32 at 2. On June 21, 2007, FDA revised the class-wide labeling, but omitted GSK's Paxil-specific language. R.589-29 at 1. FDA stressed that "it is critical that the labeling is consistent for all of these products." *Id.* at 2.

Fourth, on June 22, 2007, GSK contacted FDA to confirm that the agency had rejected GSK's Paxil-specific warning. R.589-30 at 1. On June 25, FDA responded:

> [T]he Agency has reviewed your proposed changes, and we do not believe that your product specific analysis should be included in class labeling revisions since the labeling is targeted at the class of drugs. If you would like to discuss this matter further, please submit a formal meeting request.

Id.

On June 25, 2007, GSK submitted a new supplement implementing FDA's class-wide warning. GSK reiterated that "the paroxetine specific language … would be useful for prescribers," but "underst[oo]d FDA's reasons for keeping the language

generic to the class." R.589-31 at 1. FDA approved the supplement on August 2, 2007, warning GSK that "[f]ailure to make these changes … could make your product misbranded." R.589-49 at 2. Paxil's labeling has included FDA's class-wide suicidality warning ever since. R.589-3 at 11; R.589-1 at 11.

D. Pretrial Proceedings

On July 9, 2012, plaintiff sued Mylan and GSK under Illinois law in Cook County Circuit Court, alleging that paroxetine increases the risk of suicide in adults, that it caused Dolin's suicide, and that the manufacturers negligently failed to warn of that risk. R.1-1. GSK and Mylan removed to federal court. R.1; R.73. GSK sought summary judgment, contending that plaintiff's claims failed because GSK did not manufacture, market, distribute, or sell the paroxetine Dolin ingested. R.79.

The district court denied GSK's motion in relevant part. A1. The court acknowledged that "[n]umerous courts … take a dim view of the notion that a name-brand defendant such as GSK might owe a duty of care to a consumer of the generic version of one of its drugs," and those courts "may well be right." A9-10. But the court nonetheless held that Illinois law imposes such a duty. The court also held that innovator liability comports with Hatch-Waxman, asserting that "GSK has been compensated for taking responsibility for paroxetine's design and warning label with an extended period of government-protected monopoly privileges." A11. The court dismissed the claims against Mylan on preemption grounds. A24-25

(citing *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013), and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)).

GSK sought interlocutory appeal, but the district court denied certification. R.126. GSK then sought mandamus, which this Court denied. *In re GlaxoSmithKline LLC*, No. 14-2051 (7th Cir. June 4, 2014).

GSK then moved for summary judgment under *Wyeth*, explaining that it was impossible under federal law for GSK unilaterally to give the warning Illinois law supposedly required. R.306. The district court denied the motion. A28; *see also* A50.

E. Evidence Presented at Trial

1. Dolin's Treatment and Suicide

The evidence at trial showed that Dolin suffered from a long history of work-related anxiety, and that his 2010 suicide followed a period of mounting professional pressure and uncoordinated treatment by multiple providers, none of whom was a psychiatrist.

Dolin "show[ed] signs of anxiety or depression" as early as law school. Tr.2568:17-21. The first records of Dolin taking paroxetine are from October 2005, when Dolin's "best friend" and internist, Dr. Martin Sachman, treated him for work-related anxiety. Tr.1686:1, 1704:4-1705:14. Dolin's prescription was filled with generic paroxetine manufactured by Apotex, which Dolin took for 13 months. R.589-13 at 14; Tr.1709:16-22. According to Sachman, paroxetine "effectively treat[ed] [Dolin's] anxiety." Tr.1716:25-1717:2.

In late 2006, Dolin's 125-attorney law firm merged with a multinational firm with 20 offices and 1500 lawyers. Tr.2159:12-17. Dolin was selected to co-chair the combined firm's 230-lawyer corporate and securities practice group. R.555-15 at *17:22-18:2, *70:11-71:3.[1] In January 2007, Dolin returned to Sachman, who prescribed sertraline, another SSRI. Tr.1717:25-1723:3. In February 2007, Dolin told a social worker, Sydney Reed, that he "want[ed] to get up and run." R.555-6 at *54:9-13, *73:5-16. He felt unqualified for his position and worried about supporting his family. *Id.* at *57:22-60:16, *69:3-18. That December, Dolin told Reed he had suicidal thoughts and wanted to "escape the pressure at work." *Id.* at *147:16-149:3, *149:23-150:4.

Work pressures continued to mount. Dolin described 2009 as "without a doubt [the] most challenging year ever in [his] professional career." R.589-55 at 1. His practice group missed its budget by $30 million. R.555-15 at *83:9-20. In early 2010, Dolin received several harshly negative performance reviews. R.589-59 at 3-4. In February 2010, Dolin received a "seismic shock" when the firm cut his compensation by $135,000. Tr.2020:15-17, 2483:10-14; R.589-62 at 2.

In May 2010, Dolin returned to Reed, who observed that Dolin was back in the "old fear loop." R.555-6 at *182:5-22, *178:20-179:14, *189:23-190:12. In June, Dolin returned to Sachman, who again prescribed sertraline. Tr.1795:9-11. But when Dolin complained of side-effects, Sachman switched back to paroxetine

[1] Pincites to deposition transcripts marked with an asterisk refer to internal transcript page-lines, rather than ECF pagination. All cited deposition transcripts were in evidence at trial.

because Dolin had "d[one] well on [it] in the past." Tr.1689:21-24, 1796:24-1797:2. Dolin's prescription was filled with generic paroxetine manufactured by Mylan. R.589-13 at 2.

On June 29, Dolin began seeing a third healthcare provider, psychologist Dr. Seoka Salstrom. R.555-7 at *31:3-5, *33:9-11, *51:24-52:2. Salstrom and Reed did not coordinate with each other or Sachman. Tr.1815:4-12; R.555-6 at *171:21-25, *205:21-206:9; R.555-7 at *149:3-16.

On July 14, Dolin told Reed that he was "very upset and anxious—worried about failing [his wife] and getting fired," R.555-6 at *217:3-12. He told Reed if a client's shareholder vote in two days did not go well, he might be fired. R.555-6 at *218:11-14, *218:21-219:20. The next morning, Reed advised Dolin to have Sachman prescribe a fast-acting antianxiety medication, but Dolin did not do so. R. 555-6 at *231:22-233:2; Tr.1693:14-18, 1809:9-1810:2. Dolin's client postponed the vote because Dolin had failed to complete necessary preparatory work, Tr.2224:4-2226:6; R.589-72 at 1-2, and a shareholder emailed to convey his anger, Tr.2230:18-2231:8, 2402:16-2403:1; R.589-72 at 1.

Shortly thereafter, Dolin jumped from the platform at an "L" station and was struck and killed by a train. Tr.3797:16-3798:2, 3805:8-19; R.555-5 at *51:17-52:13.

2. Dr. Sachman's Testimony

Sachman testified that he would not have prescribed Dolin paroxetine had Sachman known that "people over 24 were at risk for drug-induced suicide." Tr.1681:25-1682:10. Yet Sachman also admitted that, when he prescribed Dolin

paroxetine in 2010, he believed "that patients who took [paroxetine] may be at an increased risk for suicidal thoughts or behavior." Tr.1803:14-19. He also "recognized that the [purportedly] increased risk of suicidal thoughts or behavior was not limited to patients who were 24 or younger." Tr.1805:9-13.

Sachman also testified that, when he prescribed Dolin paroxetine in 2010, he discussed with both Dolin and plaintiff the risk of suicidal thoughts and behavior. Tr.1738:11-1741:15, 1753:15-1754:2, 1761:23-25, 1769:18-1770:9, 1803:14-19, 1805:14-1806:3. Sachman "did not limit that discussion in any way" to suggest that the risk only applied to patients under 25. Tr.1803:20-25.

Sachman also testified about GSK's April 2006 briefing document. Sachman stated that, had he been aware of the data about suicide attempts in the document, he would not have prescribed Dolin paroxetine. Tr.1759:20-1760:9. Yet Sachman also confirmed that he received and reviewed GSK's May 2006 letter and attached labeling, which Sachman admitted contained the "exact same" information and language as the briefing document. Tr.1760:18-1761:4, 1764:5-1765:17; *compare* R.589-78 at 6 *with* R.589-4 at 1, 4. Sachman received the May 2006 letter while Dolin was taking paroxetine, yet did not switch Dolin to a different drug. Tr.1770:10-18. Sachman further testified that, when he prescribed Dolin paroxetine in 2010, he believed that the 2006 Paxil-specific information about suicidality *remained* in the labeling. He did not learn that the adults-over-24 warning had been removed until four months after Dolin's suicide. Tr.1828:6-1829:3.

3. Evidence of General Causation

Plaintiff's general-causation expert, Dr. David Healy, testified that paroxetine can cause suicide, relying principally on four types of data. First, Healy relied on uncontrolled "challenge/de-challenge/re-challenge" studies—that is, case reports where a patient is never compared to a control group, but is given a drug, taken off, and restarted. Tr.316:1-16, 716:3-7, 722:17-21. Second, Healy relied on "relatedness assessments"—case reports where a blinded investigator makes a best guess about the causal relationship between a drug and a patient's symptoms. Tr.381:4-16. Third, Healy re-analyzed data GSK submitted to FDA in 1991, but admitted that his re-analysis included uncontrolled trials where no patients took placebo. R.593-6 at 4-6. Fourth, Healy relied on analyses of certain subgroups of patients within GSK's and FDA's 2006 analyses, even though FDA deemed that data insufficient even to show an association, much less causation. Tr.424:7-428:25, 437:22-440:23; *supra* pp.7-10.

On his blog and website, Healy has opined that hundreds of commonly used medications, from Benadryl to antibiotics to blood-pressure medications, cause suicide. R.549-2; R.549-4; *see* R.577-7; *see also* R.283-5 at 5-6 (Healy blog post suggesting that some who learn about drugs' side effects may "become murderous" and attempt mass killings of pharmaceutical executives or journal editors). Yet the court prohibited GSK from eliciting these opinions on cross-examination, reasoning that "[t]here are other ways to attack credibility" and establish bias. Tr.686:21-690:7; *see* Tr.626:21-627:5, 658:24-659:15, 661:3-663:19.

F. Verdict and Post-trial Proceedings

GSK moved for judgment as a matter of law during and after trial. GSK incorporated its earlier summary judgment motions and also argued that there was insufficient evidence (1) that paroxetine causes suicide, (2) that GSK had a duty to warn Sachman about a risk he already knew of, or (3) that Paxil's labeling was a cause-in-fact of Dolin's suicide. R.540, R.561, R.593. The jury returned a $3,000,000 verdict. R.569. The district court denied GSK's motions, A55, A57, and entered final judgment, A56. GSK timely appealed.

SUMMARY OF ARGUMENT

Reversal is required for three independent reasons.

First, GSK is not responsible for an injury allegedly caused by a product it did not make or market. The Illinois Supreme Court has rejected the key predicate of innovator liability. *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324 (Ill. 1990), holds that a drug manufacturer is not liable in tort absent proof it produced the injury-causing pill. For that reason, the Sixth Circuit has held that Illinois courts, like the vast majority of courts nationwide, would reject innovator liability. At a minimum, Illinois law provides no basis for a federal court sitting in diversity to recognize such a novel tort theory. In any event, innovator liability is preempted by Hatch-Waxman, which strikes a careful balance between the interests of brand and generic manufacturers. Plaintiff's theory seizes one piece of that regime—generic manufacturers' duty to match the corresponding brand labeling—and hijacks it to create limitless liability Congress never intended.

Second, plaintiff's claim is preempted under *Wyeth* because it was impossible under federal law for GSK unilaterally to give the warning plaintiff contends was required. A drug manufacturer may not unilaterally change a drug's labeling absent "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii). But FDA considered the information plaintiff now relies on *in 2007*, three years before Dolin's suicide. In any event, there is clear evidence FDA would not have approved plaintiff's warning. Indeed, it is hard to imagine clearer evidence—FDA rejected *four* separate GSK proposals for a Paxil-specific adult-suicidality warning and ordered GSK to remove such a warning from its labeling. The warning FDA mandated for all SSRIs, moreover, affirmatively states—in direct contrast to the warning plaintiff seeks—that studies "did not show an increase in the risk of suicidality … in adults beyond age 24." R.589-3 at 11.

Third, plaintiff presented insufficient evidence of multiple essential elements of her claim. The trial record contains no reliable evidence that paroxetine causes suicide in adults over 24. Plaintiff's evidence consisted of anecdotal case reports, re-analyses of uncontrolled data, and patently unreliable subgroup analyses. And even if paroxetine could cause suicidality past age 24, Dolin's physician testified that he knew about that purported risk and warned Dolin and plaintiff about it. GSK had no duty to warn Sachman about something he already knew. And since Sachman knew about the purported risk and prescribed paroxetine anyway, Paxil's allegedly deficient labeling was not a "but for" cause of Dolin's suicide.

STANDARD OF REVIEW

This Court reviews *de novo* the denial of a motion for judgment as a matter of law. *Lawson v. Sun Microsystems, Inc.*, 791 F.3d 754, 761 (7th Cir. 2015).

ARGUMENT

I. GSK Is Not Responsible for Injuries Allegedly Caused by Another Manufacturer's Drug

The district court held GSK responsible for injuries allegedly resulting from Dolin's ingestion of a drug manufactured and marketed by someone else—indeed, a GSK competitor. Holding GSK responsible for a product it did not produce, market, distribute, or profit from in any way flouts settled Illinois tort principles, contravenes scores of contrary decisions, and upends the careful balance struck by federal law.

A. Illinois Law Bars Innovator Liability

1. Innovator Liability Conflicts with Decisions of the Illinois Supreme Court and the Vast Majority of Courts Nationwide

a. In *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324 (Ill. 1990), the Illinois Supreme Court settled the bedrock tort principles that are dispositive in this case. *Smith* held that a pharmaceutical company cannot be liable for failing to warn about a drug's risks absent proof the company manufactured the particular drug that caused the plaintiff's injury. *Id.* at 340-44. That decision and its progeny preclude any theory of innovator liability under Illinois law.

Smith involved the same claim and legal theory at issue here. Smith could not identify the manufacturer of the pills her mother ingested during pregnancy, so she sued several potential manufacturers. One of Smith's claims was that the

manufacturers negligently "failed to properly test [the drug] and to adequately warn of its dangers." *Id.* at 326. And one of Smith's theories was that, even if she could not prove who made the injury-causing pills, the potential manufacturers were responsible because they participated in "obtaining FDA approval to sell" the drug, were "responsible for making [the drug] available for use," and took steps that "formed the basis of subsequent FDA approval for the manufacturing of [the drug] by other companies." *Id.* at 340. That is innovator liability in a nutshell—plaintiff seeks to hold GSK responsible for a drug it did not make because GSK obtained FDA approval for labeling later used by Mylan.

The Illinois Supreme Court categorically rejected this theory, holding that participation in developing and obtaining FDA approval for a drug, without more, is "insufficient" to create the necessary "connection between a potentially responsible defendant and the injury-causing product." *Id.* That claimed "link" fails, the court explained, "unless the plaintiff is able to prove that one of the [defendants] manufactured the [drug]," *and* the plaintiff establishes "a joint, concerted or conspiratorial effort by defendants to market [the drug]." *Id.* at 340-41. Absent concerted action with the actual manufacturer, "[t]he fact that [multiple] companies sold a similar product for similar purposes cannot fairly be held to have created a sufficient nexus such that [one] company can be responsible for the injuries caused by the others' products." *Id.*

A contrary result, *Smith* explained, would contravene three basic tort principles. First, Smith's theory would "too broadly interpret[] the duty of a drug

company and to whom it owes that duty." *Id.* at 343. While a "manufacturer owes a duty to plaintiffs who will use its drug," that "duty is not so broad as to extend to anyone who uses the type of drug manufactured by a defendant." *Id.* The duty "does not extend" to a competitor's customers, who are "unknown and unforeseeable non-users of the drug company's products." *Id.*; *see Gillenwater v. Honeywell Int'l, Inc.*, 996 N.E.2d 1179, 1200 (Ill. App. Ct. 2013) (similar).

Second, holding a manufacturer responsible based on "creation of risk or breach of duty alone" has "long been rejected in American tort law." *Smith*, 560 N.E.2d at 343-44. Negligence requires "proof that defendant breached a duty owed to a *particular plaintiff*." *Id.* at 343 (emphasis added). A manufacturer's breach of duty to its own customers therefore does not permit recovery by a noncustomer, even if the noncustomer purchased an equivalent product from another company. *Id.* at 344.

Third, holding manufacturers responsible for injuries caused by their competitors' products would "violat[e] the principle that manufacturers are not insurers of their industry." *Id.* That result would be deeply inequitable, since "[t]he companies [that] cannot prove their share will be made to pay the unattributable portion of the damages[,] … which rightfully belong to companies [that] … for some … reason are not before the court." *Id.* Moreover, forcing companies to insure against losses "arising from the products of others in the industry as well as their own," *Smith* concluded, would violate Illinois public policy. *Id.* at 341. The "added

potential for liability" would raise prices and "likely contribute to diminishing participants in the market as well as research and availability of drugs." *Id.* at 342.

Each component of *Smith*'s reasoning applies with equal or greater force here. Plaintiff never alleged that GSK conspired with Mylan, so GSK owes a duty only to its *own* customers, not Mylan's. GSK's alleged failure to warn its own customers does not justify liability for an injury to its competitor's customer. GSK is not Mylan's guarantor, and forcing GSK to insure generic paroxetine sales would be inequitable—indeed, far more inequitable than in *Smith*. There, the manufacturers would have been liable only in rough proportion to their market share. *Id.* at 344. Here, more than 80% of U.S. prescriptions are filled with generic drugs, Bill Bekrot, *U.S. Healthcare Usage and Spending Resumes Rise in 2013: Report*, Reuters, Apr. 15, 2014, but generic manufacturers are immune from liability, *Wagner*, 840 F.3d at 358-59. Innovator liability thus would hold brand manufacturers liable not just in proportion to their market share, but for the plaintiff's *whole* loss in *every* case—here, for *every* sale of paroxetine nationwide.

That regime would deter medical innovation. Litigation risks already have induced brand manufacturers to abandon efforts to develop new medicines. *See, e.g.*, Nat'l Research Council, *Developing New Contraceptives: Obstacles and Opportunities* 59 (1990), https://www.nap.edu/read/1450. Innovator liability would multiply those risks many times over. If market-share liability "likely" would harm pharmaceutical research and development, *Smith*, 560 N.E.2d at 342, holding an innovator company liable for the whole market inevitably would.

The Sixth Circuit now has held that *Smith* precludes innovator liability under Illinois law. *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014). In a decision issued after the summary judgment order in this case, the Sixth Circuit "disagreed with the *Dolin* court's holding" and held that an Illinois negligent-failure-to-warn claim would "fail for lack of product identification." *Id.* Citing *Smith*, the court explained that, "[u]nder Illinois law, a plaintiff must 'identify the supplier of the product and establish a causal connection between the injury and the product.'" *Id.* (quoting *York v. Lunkes*, 545 N.E.2d 478, 480 (Ill. App. Ct. 1989)).

b. This Court need go no further; because *Smith* rejected the principles underlying innovator liability, GSK is entitled to judgment. But the Illinois Supreme Court is not alone; there is an "overwhelming national consensus" against innovator liability. *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013). Seven federal courts of appeals have considered innovator liability under the laws of 24 states, rejecting that theory every time, both before and after the Supreme Court in *Mensing* held that claims against generic manufacturers are preempted. Those courts' reasoning echoes *Smith*. In the leading case, for example, the Fourth Circuit concluded that "Maryland courts would reject this effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused [the] injury," especially when "the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising." *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 168, 170 (4th Cir.

1994).[2] Overall, more than 100 state and federal decisions have rejected innovator liability under the laws of 29 states. R.561-23 (collecting cases through August 2016).

c. The district court's attempts to distinguish *Smith* and the landslide of nationwide precedent rejecting innovator liability are unconvincing. The court noted that in *Smith* and its progeny, the plaintiff could not identify the company that manufactured the injury-causing product, while plaintiff here can. A14-15. But that distinction cuts the other way. If a company cannot be liable when it *might or might not* be the manufacturer, a fortiori it cannot be liable when it *undisputedly is not* the manufacturer.

The district court asserted that *Smith* involved a claim for "negligence in manufacturing" and not "alleged negligence in connection with paroxetine's design and warning label." A15. That is wrong. *Smith* states: "The thrust of these causes of action is that the drug companies failed to properly test [the drug] and *to adequately warn of its dangers*." 560 N.E.2d at 326 (emphasis added).

The district court also reasoned that "neither [the Fourth Circuit in] *Foster*, nor any of the courts relying on *Foster*, addressed … whether a plaintiff injured by a product may assert that tortious conduct on the part of someone other than the

[2] *See also Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476-78 (5th Cir. 2014); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183-84 (5th Cir. 2012); *Smith v. Wyeth*, 657 F.3d 420, 424 (6th Cir. 2011); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092-94 (8th Cir. 2013); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-14 (8th Cir. 2009), *rev'd in part on other grounds*, 564 U.S. 604 (2011); *Moretti v. Wyeth, Inc.*, 579 F. App'x 563, 565 (9th Cir. 2014); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013).

product's manufacturer and extrinsic to the manufacturing process contributed to the injury." A16. The court observed that plaintiff here did not sue GSK "in lieu of the company that actually manufactured the pill" but rather "because GSK—not Mylan—was actually responsible for the pill's design and warning label." *Id.* at 16-17. In the district court's view, *Foster* and its progeny "undermine only the former type of claim." *Id.* at 17. In its post-trial order, the court described the Sixth Circuit's decision in *Darvocet* in similar terms. A51.

The plain text of *Foster*, *Darvocet*, and the scores of other cases rejecting innovator liability, however, belie the district court's characterization. *Foster* rejected a claim that brand manufacturers can be liable because "name brand manufacturers … know that generic manufacturers rely on their studies and duplicate their labeling." 29 F.3d at 169. *Darvocet* rejected a claim that "physicians reasonably and foreseeably relied on representations by Brand Manufacturers in writing prescriptions for generic [drugs] because they understand that generic drugs are required by federal law to be … labeled the same as [the corresponding brand]." 756 F.3d at 936–37. The Sixth Circuit knew what it was doing when it "disagree[d] with" the summary judgment decision here and held that Illinois courts, like "the majority of courts nationwide," would reject innovator liability. *Id.* at 943-44; *see also, e.g.*, *Guarino*, 719 F.3d at 1248, 1253; *Mensing*, 588 F.3d at 612.

In its post-trial order, the district court also asserted that a "history of misconduct with this drug … militate[d] against" following the nationwide consensus. A51. That supposed "history," however, consists of (1) two settlements

regarding off-label promotion of Paxil for use in non-adult patients, and (2) the coding of certain suicides in studies supporting Paxil's 1992 NDA, which this Court has held "do not taint the administrative history of Paxil." *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 394 (7th Cir. 2010); A37, A42-43. Regardless, this history is utterly irrelevant to the question presented—whether under Illinois law, *any* brand drug manufacturer has a duty to warn a customer of a generic competitor.

The California Supreme Court's recent decision in *T.H. v. Novartis Pharmaceuticals Corp.*, 407 P.3d 18 (Cal. 2017), does not counsel a different result here. While *T.H.* allowed an innovator-liability claim to proceed, it relied on principles Illinois courts have rejected. In California, for example, the rule holding manufacturers responsible only for the risks posed by their own products applies only to strict-liability claims. *Id.* at 37. *Smith* expressly extends that rule to negligence claims in Illinois. 560 N.E.2d at 326, 343. *T.H.* repeatedly cites *Sindell v. Abbott Laboratories*, 607 P.2d 924 (Cal. 1980), where the California Supreme Court fashioned a form of market-share liability that has been sharply criticized, has never gained wide acceptance, and was expressly rejected in *Smith*. *T.H.*, 407 P.3d at 31, 34; *Smith*, 560 N.E.2d at 331, 338, 342-44. California law "do[es] not narrowly circumscribe the kinds of relationships that must exist between the plaintiff and the defendant as a predicate to imposing a duty." *T.H.*, 407 P.3d at 37. Illinois law, by contrast, does circumscribe those relationships. *Smith*, 560 N.E.2d at 343. California views foreseeability as the "most important" factor in imposing a duty,

407 P.3d at 29, 37; *Smith* rejects the notion that "a foreseeable plaintiff" justifies imposing a duty. 560 N.E.2d at 343. In short, Illinois law governs this case, and the reasoning of the California Supreme Court does not. Other decisions recognizing innovator liability are similarly inapposite.[3]

2. Principles of Federalism Preclude a Federal Court from Recognizing Innovator Liability under Illinois Law

Even if *Smith* did not exist and Illinois law were unsettled, plaintiff's claim still fails. Federal courts must take a restrictive view of novel theories of state tort law, and no Illinois legal authority supports innovator liability.

a. A federal court sitting in diversity must predict how the state's highest court would rule if confronted with the same question of state law. *Todd v. Societe BIC, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994) (en banc). In making that prediction, federal courts have "limited discretion … with respect to untested legal theories." *A.W. Huss Co. v. Cont'l Cas. Co.*, 735 F.2d 246, 253 (7th Cir. 1984). "When given a choice between an interpretation of Illinois law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path (at least until the Illinois Supreme Court tells us differently)." *Todd*, 21 F.3d at 1412. This "restrictive approach" applies even where, as here, removal leaves the plaintiff with "no choice but to litigate [her] claim in federal

[3] *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670-74 (Ala. 2014) (en banc) (relying on foreseeability and ignoring burdens and consequences), *superseded by statute*, Ala. Code § 6-5-530(a); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010) (ruling under Vermont law, which views "foreseeability … [a]s a primary consideration" in imposing tort duties (quotation marks omitted).

court." *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 636 n.5 (7th Cir. 2007). This Court has applied this rule to reject a claim, like plaintiff's here, seeking to expand a manufacturer's duty to warn under Illinois law. *Birchler v. Gehl Co.*, 88 F.3d 518, 521 (7th Cir. 1996).

Federal courts' limited authority to extend state law rests on basic principles of federalism. Federal courts have "no basis for even considering the pros and cons of innovative theories" of state law "[a]bsent some authoritative signal from the legislature or the courts" of that state. *Dayton v. Peck, Stow & Wilcox Co.*, 739 F.2d 690, 694 (1st Cir. 1984). Federal courts must apply state law as it "presently" is, "not as it might come to be." *Id.*; *accord Rhynes v. Branick Mfg. Corp.*, 629 F.2d 409, 410 (5th Cir. 1980).

Here, innovator liability is undeniably novel. Plaintiff has never identified a single Illinois case holding a manufacturer liable in tort for an injury caused by another company's product. Even the district court, which disregarded *Smith*, acknowledged that innovator liability is—at best—"a question of first impression in Illinois." A7. The court should have stopped right there and rejected the claim.

b. Lacking any Illinois authority affirmatively supporting innovator liability, the district court relied on general negligence principles. That was improper; abstract principles do not authorize tort innovation by federal courts. Regardless, Illinois negligence principles preclude innovator liability.

"[T]he touchstone of [a] court's duty analysis is to ask whether a plaintiff and a defendant stood in such a *relationship* to one another that the law imposed upon

the defendant an obligation of reasonable conduct for the benefit of the plaintiff." *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1097 (Ill. 2012) (quotation marks omitted). The existence of that relationship "involves considerations of public policy," and turns on factors including "the reasonable foreseeability of the injury," "the magnitude of the burden of guarding against the injury," and "the consequences of placing that burden on the defendant." *Id.* Each factor weighs against innovator liability.

The district court reasoned that "the foreseeability of Plaintiff's injury … should not be controversial" because "it was no surprise" that competitors would sell generic paroxetine with Paxil's labeling. A10. But that reasoning "stretches foreseeability too far." *Darvocet*, 756 F.3d at 944. "[G]eneric consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control." *Id.*; *accord Foster*, 29 F.3d at 171. Once any exclusivities have expired, brand manufacturers have no say over whether, how, and to what extent a generic manufacturer enters the market. Brand manufacturers also have no control over whether state laws permit or require pharmacists to dispense generic drugs in place of brands. And four justices of the California Supreme Court have opined that a brand manufacturer may be held liable even if it stops selling its own product entirely, as GSK did when it sold the Paxil NDA in 2014. *See T.H.*, 407 P.3d at 40-47.

Regardless, "the existence of a legal duty is not to be bottomed on … foreseeability alone," which courts must "balance … against the burdens and

consequences that would result from the recognition of a duty." *Hutchings v. Bauer*, 599 N.E.2d 934, 935 (Ill. 1992). The district court asserted that "[g]uarding against the injury … could be as simple as updating the warning label." A11. But brand manufacturers have the duty to update their labeling regardless of innovator liability. The real issue is that medical knowledge is uncertain and evolving, making it difficult to predict what warnings FDA will approve or juries will require, and innovator liability massively magnifies the financial consequences of that uncertainty. As this case demonstrates, even when manufacturers research and attempt to warn about potential risks, patients may sue anyway. The burden from innovator liability, moreover, bears no relation to manufacturers' profits. As the district court recognized elsewhere in its opinion, a "name-brand manufacturer sees no proportionate increase in earning commensurate with the increased risk exposure" from additional generic sales. A23. Innovator liability thus would punish innovative companies and impede the development of new life-saving medicines. The district court's duty analysis mentioned none of this, even though Illinois's Supreme Court "is acutely aware of the social desirability of encouraging the research and development of beneficial drugs." *Smith*, 560 N.E.2d at 342.

B. Federal Law Preempts Innovator Liability

Even if Illinois law recognized innovator liability, that theory would be preempted. State law is preempted "to the extent of any conflict with a federal statute," including "when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillman v. Maretta*,

569 U.S. 483, 490 (2013) (quotation marks omitted). Innovator liability conflicts with the Hatch-Waxman Act's careful statutory balance between pharmaceutical competition and innovation.

1. A court considering obstacle preemption begins "by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). Here, the goal was balance: Congress enacted Hatch-Waxman to spur the introduction of cheaper generic drugs while preserving brand manufacturers' incentives to develop new drugs.

As explained, Hatch-Waxman allows generic manufacturers to gain FDA approval through an abbreviated application that "piggy-back[s] on the [brand manufacturer]'s approval efforts." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2010); *supra* pp.4-5. The statute also creates procedures for resolving patent disputes before generic entry and provides an incentive for generic manufacturers to bring patent challenges. *Actavis*, 570 U.S. at 142-44. In exchange for these provisions, which reduce the economic incentives for brand manufacturers to develop new drugs, Hatch-Waxman offers corresponding protections that increase those incentives. For example, brand manufacturers can extend the terms of their patents by up to five years to compensate for FDA regulatory delays. 35 U.S.C. § 156(g)(6). And generic manufacturers cannot seek approval until three to five years after approval of the brand drug. 21 U.S.C. § 355(c)(3)(E)(ii)-(iv); *see also* §§ 355a(b), 355f(a), 360cc(a) (extended exclusivities for pediatric studies, qualified infectious-disease products, and "orphan" drugs approved to treat rare diseases).

Congress carefully calibrated these provisions so as to preserve brand manufacturers' incentives to develop innovative new drugs. Rep. Waxman described the bill as "a very difficult and complex effort to strike a balance between" facilitating generic entry and rewarding innovation. 130 Cong. Rec. 24,435. Sen. Hatch found the bill "remarkable … for its balance and for the breadth of its support." 130 Cong. Rec. 15,846; *see* H.R. Rep. No. 98-857(II), at 7 (1984) ("[T]he proponents of the legislation urged its adoption as the best possible compromise between two competing economic interests."); *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1347 (Fed. Cir. 2007) (Gajarsa, J., concurring in denial of reh'g en banc) (collecting citations). Even the statute's structure (with Title I devoted to generic entry and Title II devoted to exclusivity extensions) and its formal name (the Drug Price Competition and Patent Term Restoration Act) reflect balance and compromise. *See* Pub. L. No. 98-417, 98 Stat. 1585.

2. State-law innovator-liability claims would overturn the balance Congress so carefully calibrated. Statutes that "strike a balance between competing … objectives lend themselves to a finding of conflict preemption." *Farina v. Nokia Inc.*, 625 F.3d 97, 123 (3d Cir. 2010). The Supreme Court, for example, has found obstacle preemption where a state law "conflict[ed] with the careful framework Congress adopted" in immigration laws, *Arizona v. United States*, 567 U.S. 387, 402 (2012), deviated from the "middle path" Congress steered in an economic sanctions statute, *Crosby*, 530 U.S. at 378, and "clashe[d] with the balance struck by Congress in our patent laws," *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141,

152 (1989). *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996) (no preemption because "this [is] quite unlike a case in which the Federal Government has weighed … competing interests"). The courts of appeals, including this Court, likewise have invalidated state laws that purport to re-weigh a balance Congress has already struck. *E.g.*, *In re Vehicle Carrier Servs. Antitrust Litig.*, 846 F.3d 71, 87 & n.18 (3d Cir. 2017); *Columbia Venture, LLC v. Dewberry & Davis, LLC*, 604 F.3d 824, 831 (4th Cir. 2010); *MITE Corp. v. Dixon*, 633 F.2d 486, 495-98 (7th Cir. 1980), *aff'd*, 457 U.S. 624 (1982).

Bonito Boats is instructive. The Supreme Court there invalidated a Florida statute barring duplication of the shape of vessel hulls. 489 U.S. at 144. As the Court explained, "[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Id.* at 146. "Where it is clear how the patent laws strike that balance[,] … that is not a judgment the States may second-guess." *Id.* at 152. The Florida statute, however, offered "patent-like protection" to inventions that were unpatented or unpatentable. *Id.* at 164. In so doing, Florida "substantially reduce[d] th[e] competitive incentive" that reverse engineering provides to inventors, "eroding the general rule of free competition upon which the attractiveness of the federal patent bargain depends." *Id.* at 161.

The Federal Circuit applied this logic in *Biotechnology Industry Organization v. District of Columbia*, holding that Hatch-Waxman preempted a D.C. law capping

the prices of patented prescription drugs. 496 F.3d 1362, 1365 (Fed. Cir. 2007). Hatch-Waxman is incorporated into the patent laws, the court noted, and embodies the "dialectic tension" between "reward[ing] innovators with higher profits" and "keep[ing] prices reasonable for consumers." *Id.* at 1373. "By penalizing high prices[,] … the District … chose[] to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374. But "the proper balance between innovators' profit and consumer access to medication … is exclusively one for Congress to make." *Id.* The D.C. law therefore "st[ood] as an obstacle to the federal patent law's balance of objectives as established by Congress." *Id.*

Innovator liability would improperly rebalance Hatch-Waxman's statutory objectives in just the same way. As *Foster* noted, "[t]he premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer's drug has been consumed." 29 F.3d at 170. Instead of receiving patent and regulatory exclusivities in exchange for easier generic entry, brand manufacturers *also* would have to insure generic sales against state tort claims. Plaintiff's theory would take one piece of the Hatch-Waxman regime—generic manufacturers' duty to match brand labels—and hijack it to create market-wide liability Congress never imagined. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-53 (2001). Indeed, innovator liability could impose costs "large enough

… to offset the very benefits Congress intended to confer." *Xerox Corp. v. Cty. of Harris*, 459 U.S. 145, 153 (1982).

In *Mensing*, where the Supreme Court held that Hatch-Waxman preempts state-law failure-to-warn claims against generic manufacturers, all nine justices assumed that a plaintiff injured by a generic drug cannot sue the brand manufacturer. The five-justice majority acknowledged its holding dealt generic consumers an "unfortunate hand"—*i.e.*, it denied them a remedy. 564 U.S. at 625. And the four-justice dissent criticized the majority precisely because "a consumer harmed by inadequate warnings [now] can obtain relief" only if "her pharmacist filled her prescription with a brand-name … drug." *Id.* at 627. If a consumer "takes a generic drug, … she now has no right to sue." *Id.* at 643. FDA has made the same assumption. *Guilbeau*, 2018 WL 476343, at *8 (noting FDA's view that "access to the courts is dependent on whether an individual is dispensed a brand name or generic drug").

3. The district court held that "GSK has been compensated for taking responsibility for paroxetine's design and warning label with an extended period of government-protected monopoly privileges" for Paxil. A11; *see also* A5, A23 (similar). That reasoning grossly distorts the quid pro quo embodied in Hatch-Waxman. The statute grants brand manufacturers extended exclusivities in exchange for eased generic entry. Nothing in the statute's text, structure, or legislative history suggests Congress intended new exclusivities to compensate brand manufacturers for insuring generic sales against state-law labeling claims.

II. Plaintiff's Claim Is Preempted Because Federal Law Prohibited GSK From Providing Plaintiff's Requested Warning

Innovator liability aside, plaintiff's claim is independently preempted under *Wyeth*. The Supreme Court there held that FDA's approval of a drug's labeling preempts state-law failure-to-warn claims where (1) the manufacturer lacks "newly acquired information" allowing it to "unilaterally strengthen its warning" under FDA regulations, *or* (2) "clear evidence" shows FDA "would not have approved" the warning state law requires. 555 U.S. at 569, 571-73.

Wyeth preemption is a "legal" question, *Guilbeau*, 2018 WL 476343, at *10; *Mason*, 596 F.3d at 390, and plaintiff's claim here is preempted as a matter of law for both of these reasons. Plaintiff claims that GSK should have warned about a risk of suicidality for all age groups. But GSK had no basis for a unilateral labeling change, and it is clear four times over that FDA "would not have approved" the warning plaintiff seeks, given that FDA repeatedly *rejected* it.

A. GSK Had No Basis for a Unilateral Labeling Change

State law is preempted to the extent it "directly conflict[s]" with federal law, including "where it is impossible for a private party to comply with both state and federal requirements." *Mensing*, 564 U.S. at 618. The critical question for "impossibility preemption" is "whether the private party could *independently* do under federal law what state law requires of it." *Id.* at 620 (emphasis added). Whether a party can *propose* a change for approval by a federal agency is irrelevant. *Id.* at 624. For drug manufacturers, FDA's CBE regulation provides the only mechanism for "'to unilaterally strengthen [a] warning' without prior FDA

approval." *Id.* at 615 (quoting *Wyeth*, 555 U.S. at 573); *see* 21 C.F.R. § 314.70. Where "the CBE process [i]s not open," *Mensing*, 564 U.S. at 624—as in *Mensing*, *id.* at 614-15, and *Guilbeau*, 2018 WL 476343, at *6-10, for example—failure-to-warn claims are preempted.

The CBE process is not open unless manufacturers have "newly acquired information," meaning "data, analyses, or other information not previously submitted to the Agency." 21 C.F.R. §§ 314.70(c)(6)(iii), 314.3(b). Failure-to-warn claims thus are preempted if manufacturers have no information FDA has not already seen. *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015). That rule makes "pragmatic sense"—it "lets the FDA be the exclusive judge of safety and efficacy based on information" it considers, "while allowing the states to reach contrary conclusions when new information not considered by the FDA develops." *Id.*; *see also In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 185 F. Supp. 3d 761, 768-71 (D.S.C. 2016).

Here, plaintiff's claim hinges on information that indisputably was "previously submitted" to FDA. 21 C.F.R. § 314.3(b). In evaluating the relationship between antidepressants and suicidality, FDA will consider "information from placebo-controlled trials only." R.308-8 at 61. And plaintiff has identified only two even potentially relevant analyses of placebo-controlled data. First, plaintiff relies on a subgroup analysis of a secondary endpoint in GSK's 2006 re-analysis. R.584 at 23. But GSK submitted that analysis to FDA twice in April 2006. *Supra* pp.7-8.

After that point, GSK could not have unilaterally changed Paxil's labeling again based on the same "previously submitted" information without violating the CBE regulation. Second, plaintiff has pointed to a subgroup analysis from FDA's 2006 meta-analysis. R.584 at 23-24. But FDA obviously considered its own analysis when it ordered standardized suicidality warnings for all SSRIs in mid-2007. *Supra* pp.8-9. Again, a further unilateral labeling change based on the same information FDA already considered would have violated the CBE regulation.

In short, once FDA considered these analyses and rejected GSK's proposals in mid-2007, the unilateral CBE process was no longer open, because GSK lacked "newly acquired information." Plaintiff's theory is that GSK should have tried again. But the CBE regulation *barred* GSK from trying again independently. GSK thus was situated identically to the manufacturers in *Mensing* and *Guilbeau*: To have provided the warning plaintiff seeks at the relevant time—here, by 2010, when Dolin took paroxetine—GSK would have needed "the Federal Government's special permission." *Mensing*, 564 U.S. at 623-24. GSK therefore could not "independently satisfy [the] state duties" plaintiff seeks to enforce. *Id.* at 624. "Since unilateral changes to [Paxil]'s label were not possible, state-law claims alleging a failure to take that action are preempted." *Guilbeau*, 2018 WL 476343, at *10.

B. FDA Would Not Have Approved Plaintiff's Warning

Even if GSK could have tried to give plaintiff's requested warning unilaterally, her claim still is preempted. FDA "retains authority to reject" unilateral labeling changes, and there is "clear evidence" FDA "would … have"

rejected plaintiff's warning. *Wyeth*, 555 U.S. at 571. The evidence could hardly be clearer: FDA *did* reject the warning.

1. *Wyeth* declined to "clarify what constitutes 'clear evidence,'" *Mason*, 596 F.3d at 291, but the Supreme Court's analysis compels the conclusion that plaintiff's claim here is preempted. *Wyeth* gave four reasons the brand manufacturer there lacked "clear evidence": (1) neither "FDA [n]or the manufacturer gave more than passing attention" to the risk at issue, (2) the manufacturer had not "supplied the FDA with an evaluation or analysis" of that risk, (3) the manufacturer never "attempted to give the kind of warning required" under state law, and (4) FDA "had not made an affirmative decision" to reject the warning. 555 U.S. at 572-73.

All four of these critical facts are present here. Both FDA and GSK gave far more than "passing attention" to the risk of adult suicidality. *Id.* at 572. FDA undertook a major analysis of suicidality data for all antidepressants, including SSRIs, discussed the results in a public hearing, and ordered a new class-wide suicidality warning. *Supra* pp.7-9. For its part, GSK conducted its own re-analysis, which GSK "supplied" to FDA as part of an "attempt[] to give the kind of warning" plaintiff now requests. 555 U.S. at 572; *supra* pp.7-8. Indeed, GSK unilaterally gave an adult-suicidality warning, and four times sought approval to keep it. *Supra* pp.8-11. But FDA "made an affirmative decision" to reject GSK's proposals and ordered GSK to remove the warning, 555 U.S. at 572, because FDA "did not believe that

[GSK's] product specific analysis should be included in the class labeling revisions," R.589-31 at 2; *supra* pp.9-11. *Wyeth* forecloses plaintiff's claim.

So do appellate decisions applying *Wyeth*. This Court has found "clear evidence" where, as here, FDA "refus[es] to require a reference to [the risk in question], when it had been asked to do so in the submission to which the agency was responding." *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010). The Sixth Circuit has held that "clear evidence" exists even where FDA rejects a warning by "informal" means, such as email or telephone. *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 386-87 (6th Cir. 2017). The Tenth Circuit has described an FDA rejection letter as not just "clear evidence," but a "smoking gun." *Cerveny*, 855 F.3d at 1103 n.11. Here, there is not just one "smoking gun," but four.

This Court's decision in *Mason* is not to the contrary. *Mason* rejected a *Wyeth* defense involving Paxil, but Mason's suicide occurred in 2003, years before GSK repeatedly but unsuccessfully sought FDA approval to warn about suicidality past age 24. 596 F.3d at 389, 396. Moreover, Mason was 23. *Id.* at 389. GSK has warned about suicidality through age 24 since 2006, and FDA approved such a warning as part of the class-wide warning in 2007. But FDA has repeatedly rejected any suicidality warning for patients over 24, like Dolin. *Supra* pp.9-11.

In re Fosamax (Alendronate Sodium) Product Liability Litigation, 852 F.3d 268 (3d Cir. 2017), *petition for cert. filed* (Aug. 22, 2017) (No. 17-290), is similarly inapposite. The court there erroneously viewed *Wyeth* preemption as a factual question for the jury, *id.* at 285-86, 293, 297-99—a view this Court rejected in

Guilbeau, 2018 WL 476343, at *10, and *Mason*, 596 F.3d at 390. And FDA eventually *approved* the warning the *Fosamax* plaintiffs sought, 852 F.3d at 296-97, rather than consistently rejecting it, as here.

2. In addition to FDA's repeated rejections, the agency's mandated class warning states: "Short term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24." R.589-3 at 11. That statement flatly contradicts the warning plaintiff demands in this case—that studies *did* show an increase in suicidality in adults over 24. *See* R.584 at 16.

By statute, a drug is impermissibly "misbranded" if the labeling is "misleading," including by omitting material facts. 21 U.S.C. §§ 321(n), 331(a). A manufacturer's duty to disclose material facts, however, "does not … [p]ermit a statement of differences of opinion with respect to warnings." 21 C.F.R. § 1.21(c). FDA has explained: "Inclusion of conflicting opinions" in warnings "would result in such uncertainty and confusion that the usefulness of such warnings in protecting the public against possible harm would be severely undermined, if not destroyed." 40 Fed. Reg. 28,582, 28,583 (July 7, 1975). "Although [warnings] are often the subject of intense debate, [FDA] has never permitted drug labeling to reflect such debate." 39 Fed. Reg. 33,229, 33,231 (Sept. 16, 1974).

Labeling that reflects debate, however, is precisely what plaintiff demands. After participating in the debate over SSRIs and suicidality for years, FDA determined that studies do not show an increased risk of suicidality past age 24,

and ordered all SSRI labeling, including Paxil's, to state as much. Labeling that *also* stated that studies *do* show an increased suicidality risk beyond 24 would inevitably confuse doctors and patients—exactly what the prohibition against conflicting opinions is intended to prevent. Neither plaintiff nor the district court has ever reconciled plaintiff's requested warning with FDA's mandated class-wide warning. To the contrary, plaintiff has admitted this "direct conflict." R.325 at 17.

C. A Separate Supplement or Meeting Request Would Not Have Enabled GSK To Provide Plaintiff's Requested Warning

The district court held that plaintiff's claim survived *Wyeth* because GSK did not "take[] the FDA up on its request to schedule a formal meeting or submit a separate supplement." A28; *see also* A50. That rationale cannot save plaintiff's claim for two independent reasons.

First, the district court's reasoning is nonresponsive to the dispositive point that GSK had no basis to change its labeling without prior FDA approval. Requesting a formal meeting or submitting another supplement are ways GSK could have *sought* FDA approval; they are not ways GSK could have acted *without* FDA approval.

As explained, a unilateral labeling change requires "newly acquired information," 21 C.F.R. § 314.70(c)(6)(iii). Requesting a formal meeting would not have given GSK new information. And as for the court's proposed "separate supplement," GSK submitted *two* CBE supplements with Paxil-specific adult-suicidality warnings, and by June 2007 FDA had rejected both (along with GSK's other requests). *Supra* pp.8-11. After that point, as plaintiff's regulatory expert

admitted, GSK learned no new information. Tr.1526:25-1529:4. GSK therefore could not have changed Paxil's labeling unilaterally.

Second, the possibility of a formal meeting or yet another supplement does not suggest FDA would have approved plaintiff's warning. Brand manufacturers *always* have those rights. *See* 21 C.F.R. § 314.70; 82 Fed. Reg. 61763 (Dec. 29, 2017). Holding that such rights defeat preemption thus would render *Wyeth* preemption a dead letter. The question is not whether GSK could have continued asking for a warning, but whether FDA would have approved it. *Rheinfrank*, 680 F. App'x at 386.

The answer to that question is "no." The district court suggested that FDA might have approved an adult-suicidality warning "outside the class warning," A50, rather than "within" it, as GSK proposed, R.589-26 at 1. That is inconceivable. FDA is an expert agency charged with protecting public health. By June 2007, it had been studying SSRIs and suicidality for decades and had rejected *four* GSK proposals for a Paxil-specific warning because the agency wanted "standardized labeling pertaining to adult suicidality with all [antidepressants]." R.589-23 at 1. Yet on the district court's theory, the only reason FDA did not order a Paxil-specific warning, and has not done so to this day, is that—even though such a warning purportedly would protect patients from a life-threatening risk—FDA disliked *where* GSK placed the warning on the labeling. That is insulting to FDA's dedicated public servants.

What is more, had FDA rejected GSK's proposed labeling based on placement rather than substance, the agency would have violated federal law. Disagreement about placement is not a valid ground for denying a supplement. *See* 21 U.S.C. § 355(d). Moreover, legislation enacted in September 2007, shortly after FDA rejected GSK's last warning request, mandates that if FDA "becomes aware of new safety information that [the agency] believes should be included in the labeling of [a] drug," it must "promptly notify" the manufacturer. § 355(o)(4)(A)-(B); Pub L. No. 110-85, § 901 (2007). If FDA "disagrees" with the manufacturer's response, FDA must "*initiate discussions to reach agreement* on whether the labeling for the drug should be modified[,] … and if so, the contents of such labeling changes." 21 U.S.C. § 355(o)(4)(C) (emphasis added). That FDA has not initiated such discussions to this day confirms that FDA rejected GSK's proposals because it concluded that paroxetine is not associated with suicidality past age 24.

Ultimately, the decision below rests on speculation that, so long as GSK retained any way to ask FDA to reconsider an adult-suicidality warning, FDA might have approved one. That sort of "conjecture[]" cannot defeat preemption. *Mensing*, 564 U.S. at 621. Otherwise, conflict preemption would be "all but meaningless." *Id.* If speculation about FDA changing its mind could defeat preemption, moreover, manufacturers would no longer take "no" for an answer. FDA would have to waste resources responding to futile manufacturer requests, rather than protecting public health. *Wyeth* does "not … impos[e] upon [a] drug manufacturer a duty to

continually 'press' an enhanced warning which has been rejected by the FDA." *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1279 (W.D. Okla. 2011).

III. Plaintiff Presented Insufficient Evidence of Causation and Duty

This Court independently should reverse because the evidence was insufficient to establish the essential elements of causation and breach of duty. A defendant is entitled to judgment as a matter of law where the plaintiff fails to adduce "a legally sufficient amount of evidence from which [the jury] could reasonably derive its verdict." *Massey v. Blue Cross-Blue Shield of Ill.*, 226 F.3d 922, 924 (7th Cir. 2000). There must be "substantial evidence—more than a mere scintilla—that would have permitted the jury to find in [plaintiff's] favor." *Mut. Serv. Cas. Ins. Co. v. Elizabeth State Bank*, 265 F.3d 601, 612 (7th Cir. 2001). No reasonable jury could have imposed liability on these facts.

A. Plaintiff Presented Insufficient Evidence that Paroxetine Causes Suicide in Adults over 24

To prove causation in a pharmaceutical case, a plaintiff must show, based on scientifically reliable evidence, that the medication is capable of causing the injury at issue. *Donaldson v. Cent. Ill. Pub. Serv. Co.*, 730 N.E.2d 68, 78 (Ill. App. Ct. 2000), *aff'd*, 767 N.E.2d 314 (Ill. 2002); *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 642 (7th Cir. 2010). "[S]peculation cannot be the basis of a jury verdict," *Garrett v. Barnes*, 961 F.2d 629, 634 (7th Cir. 1992), and "speculative," "theoretical," or "vague" evidence of causation is inadequate, *In re Human Tissue Prod. Liab. Litig.*, 582 F. Supp. 2d 644, 687 & n.46 (D.N.J. 2008). Rather, "establishing causation requires … repeated, consistent, statistically significant human epidemiological

findings, and studies which address suspected confounders and biases." *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 498 n.89 (E.D. Pa. 2016); *see Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1215-16 (10th Cir. 2002) (rejecting studies that failed to "show[] a statistically significant link between" the drug and the injury); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 n.16 (11th Cir. 1999) ("[S]howing association is far removed from proving *causation*.").

Plaintiff failed to present evidence from which a reasonable jury could conclude that paroxetine causes suicide in patients over 24. That is no surprise; the absence of even an association is precisely why FDA prohibited GSK from adding the warning plaintiff seeks.

1. Plaintiff's general-causation expert based his conclusions principally on case reports and relatedness assessments. Dr. Healy testified about two patients who had suicidal thoughts on paroxetine, stopped when taken off, and again had suicidal thoughts when put on a different SSRI. Tr.317:8-12. He described these challenge/de-challenge/re-challenge cases as "conclusive[]" proof of causation. Tr.317:12-16. Healy also testified about instances where an investigator determined that a given patient's symptoms—which ranged from constipation to akathisia (restlessness)—were "definitely," "probably," or "possibly" related to paroxetine. *E.g.*, Tr.395:25-397:6, 403:1-406:14.

Case reports, which "describe isolated and uncorroborated instances of medical events occurring coincident with the use of a prescription drug," *Soldo v.*

Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 462 (W.D. Pa. 2003), are "at the bottom of the evidence hierarchy," Reference Manual on Scientific Evidence 724 (3d ed. 2011) (*Reference Manual*). "[B]ecause there is no comparison group" against which such reports are evaluated, they are typically "not even sufficient to show association"—much less causation. *Id.* at 218. Federal courts overwhelmingly reject case reports as "not scientifically valid proof of causation," *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001), "not reliable enough … to demonstrate the causal link," *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002), and "insufficient to create a material question of fact on general causation," *Zoloft*, 176 F. Supp. 3d at 497. And uncontrolled challenge/de-challenge/re-challenge methods cannot convert an unreliable case report into cognizable evidence. *Cf.* Tr.716:3-7. "[D]echallenge/rechallenge tests are still case reports and do not purport to offer definitive conclusions as to causation." *Rider*, 295 F.3d at 1200.

The same goes for relatedness assessments, which are just a type of case report. Tr.381:4-16. Like case reports generally, relatedness assessments are scientifically invalid as proof of causation. *In re Accutane Prods. Liab.*, 2007 WL 1288354, at *1-2 (M.D. Fla. May 2, 2007); *Soldo*, 244 F. Supp. 2d at 464-65. Case in point: Healy admitted that investigators blinded to whether patients were taking paroxetine or placebo sometimes rated adverse events as "definitely related" or "probably related" to medication in patients taking placebo. Tr.706:13-22.

2. Plaintiff's experts' re-analyses of clinical-trial data did not provide sufficient evidence of causation either. Healy testified that in his "re-analysis" of data in Paxil's original 1991 submissions to FDA, he discovered an association between paroxetine and suicide. But his re-analysis included not only placebo-controlled trials, but also uncontrolled trials. *See* R.593-6 at 4-6. Without a control group, it is impossible to distinguish mere association from causation. That is especially so here: "Having a control group is important when analyzing suicidal behavior data because suicidal behavior is a symptom of depression and related diseases." *Mason*, 596 F.3d at 394 n.8; *see* R.308-8 at 61.

Healy and plaintiff's regulatory expert, Dr. David Ross, also relied heavily on GSK and FDA subgroup analyses, which they contended showed that paroxetine increased suicidality 6.7- and 2.76-fold, respectively. Tr.424:7-428:25, 437:22-440:23, 1107:11-1108:22, 1130:11-1131:9. But the problem inherent in subgroup analyses, which run multiple comparisons using a single data set, is that, "[i]f enough comparisons are made, random error almost guarantees that some will yield 'significant' findings, even when there is no real effect." *Reference Manual* at 256; *accord Erica P. John Fund, Inc. v. Halliburton Co.*, 309 F.R.D. 251, 265 (N.D. Tex. 2015). Ross agreed, likening subgroup analysis to "shooting an arrow and then drawing a bull's-eye around it afterwards." Tr.1380:19-25. That is why FDA itself cautioned that the significance of the purported 2.76-fold increase "must be discounted for the large number of comparisons being made." R.589-14 at 23;

Tr.2778:14-2779:23. The 6.7-fold increase in GSK's analysis must be discounted for the same reason.

Undisputed testimony, moreover, showed that the 6.7-fold increase in GSK's analysis stemmed from decreased suicidality in the placebo group, not increased suicidality among paroxetine users. In the subgroup, only *one* out of 1,978 patients taking placebo—0.05%—experienced suicidality, compared to 31 of 12,895 people taking placebo—0.24%—in FDA's much larger analysis. Tr.2747:25-2748:22, 2750:18-23; *compare* R.589-21 at 11 *with* R.589-51 at 8 tbl.12. No reasonable jury could have relied on this subgroup analysis as evidence that paroxetine causes suicide.

3. Although plaintiff bore the burden of proof, GSK put on overwhelming evidence that paroxetine does not cause suicide in adults over 24. This included multiple placebo-controlled analyses conducted or reviewed by FDA:

- GSK's 2002 reanalysis of 1991 Paxil data, which found no statistically significant association between paroxetine and suicide or suicide attempts, R.589-19 at 8; Tr.3154:21-3155:13;
- GSK's 2006 analysis of Paxil data, which found "no statistically significant difference between adults with MDD treated with paroxetine compared to placebo" for definitive suicidal behavior or ideation, R.589-21 at 11;
- GSK's 2006 analysis, which found "no evidence" of definitive suicidal behavior or ideation or suicidal behavior alone when assessing all trials, all depression trials, or all non-depression trials, *id.* at 13; and
- FDA's comprehensive analysis of all antidepressants, including SSRIs, which concluded that the "net effect appears to be neutral on suicidal behavior but possibly protective for suicidality for adults between the ages of 25 and 64 and to reduce the risk of both suicidality and suicidal behavior in subjects aged 65 years and older," R.589-14 at 8, 44.

In the decades since Paxil was approved, and in the seven years since Dolin's suicide, FDA has never taken any action to add plaintiff's proposed warning, despite "employ[ing] a reduced standard (vis-à-vis tort liability) for gauging causation." *Glastetter*, 252 F.3d at 991; *accord Hollander*, 289 F.3d at 1215. To this day, Paxil's labeling retains the class-wide language FDA mandated in 2007—the same language plaintiff complains of here—because there is simply no evidence that Paxil is associated with, much less causes, suicide in adults over 24. No reasonable jury could have concluded otherwise.

4. The district court failed to consider any of this evidence. Instead, it relied entirely on Healy's testimony that "akathisia, emotional blunting and decompensation" are mechanisms by which paroxetine could cause suicidality. A45. But plaintiff's regulatory expert admitted that "none" of these "possible mechanisms" have been "scientifically confirmed." Tr.1641:23-1642:15. Plaintiff's third expert, Dr. Joseph Glenmullen, testified that he knows of no placebo-controlled studies showing a statistically significant association between akathisia and suicidality. Tr.2284:21-2285:16. "[P]roof of causation must be such as to suggest 'probability' rather than mere 'possibility,' precisely to guard against raw speculation by the fact-finder." *Sakaria v. Trans World Airlines*, 8 F.3d 164, 172-73 (4th Cir. 1993). Healy's speculation about "possible mechanisms" cannot support a jury verdict on causation.

B. Dr. Sachman's Actual Knowledge of Paroxetine's Purported Risk Precludes Liability

Even if Paxil could cause suicide in adults over 24, GSK had no duty to warn under Illinois law because Sachman, Dolin's prescribing physician, testified that he independently knew of the purported risk *and* actually warned Dolin and plaintiff about it. Moreover, Sachman's informed decision to prescribe Dolin paroxetine—despite his knowledge of the purported risk—breaks the chain of causation. Both issues independently require reversal.

1. GSK Had No Duty to Warn Dr. Sachman of Something He Already Knew

Illinois law does not require prescription-drug manufacturers to warn *patients*. Manufacturers instead have a duty to warn prescribing physicians—the "learned intermediar[ies]"—who in turn must convey appropriate warnings to patients. *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392 (Ill. 1987). Consequently, manufacturers have no duty to warn prescribing physicians who are *already* aware of the information at issue. *Hansen v. Baxter Healthcare Corp.*, 723 N.E.2d 302, 312 (Ill. App. Ct. 1999). "[T]here is no duty to warn of a risk that is already known by those to be warned." *Proctor v. Davis*, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997).

GSK had no duty to warn Sachman in 2010 of any association between paroxetine and suicidality in adults over 24 because Sachman was already aware of that purported risk. Sachman testified that, when he prescribed Dolin paroxetine in June 2010, he knew "that patients who took that medication may be at an increased

risk for suicidal thoughts or behavior." Tr.1803:14-19. Sachman understood that he "needed to be on the lookout for worsening depression, suicidal thoughts or behavior, [and] akathisia … *in any patient*" taking paroxetine—not just patients under 25. Tr.1779:17-23 (emphasis added). Sachman testified that he was on the lookout for akathisia in particular "because [akathisia] was described as one of the … potential side effects of … paroxetine," and "could be [associated with] suicidal thoughts or behavior." Tr.1751:13-17. Sachman also "recognized that the increased risk of suicidal thoughts or behavior" purportedly associated with paroxetine "*was not limited to patients who were younger than 24*." Tr.1805:9-13 (emphasis added). Sachman also received and reviewed GSK's 2006 letter and was not aware until after Dolin's death that FDA had required GSK to remove that information from the labeling. Tr.1828:6-1829:3.

Sachman also testified repeatedly that he *actually warned* both Dolin and plaintiff of a risk of suicidality. Sachman testified that, when he first started Dolin on paroxetine in 2005, he advised both Dolin and plaintiff to be alert to potential "worsening of depression" and "suicidal ideation." Tr.1737:13-1740:2, 1753:15-1754:2. Sachman received GSK's May 2006 letter and testified that he most likely communicated the information in it to Dolin. Tr.1761:18-25, 1769:13-22. In 2010, when Sachman restarted Dolin on paroxetine, he again advised Dolin and plaintiff to watch for signs of "agitation, increased restlessness or insomnia, panic attacks, worsening depression, or suicidal thoughts or behavior." Tr.1803:7-13, 1805:14-23.

Sachman "did not limit" these warnings "in any way" to suggest that a suicidality risk applied only to patients under 25. Tr.1803:20-25; *see* Tr.1804:1-1805:8.

In this regard, the facts here mirror those meriting summary judgment in *Higgins v. Forest Labs.*, 48 F. Supp. 3d 878 (W.D. Va. 2014). Like Sachman, the prescribing physicians in *Higgins* testified that, before treating the 60-year-old decedent, they were aware "that SSRIs, while generally effective in treating anxiety and depression, could cause an increased risk of suicidality in certain patients, and that, as such, patients should be closely monitored." *Id.* at 893; *see* Tr.1779:17-23. They further testified, like Sachman, that "it was their standard practice to instruct the patient to be on the lookout for increased anxiety or depression." 48 F. Supp. 3d at 893; *see* Tr.1737:1-12. Because the decedent's physicians were "independently aware of the risks [plaintiff] claims [the manufacturer] should have warned [of]," the court held, "there [was] no basis upon which any reasonable jury could impose failure to warn liability." 48 F. Supp. 3d at 893. So too here.

The district court relied on Sachman's testimony that he believes Paxil's current labeling does not warn of the purported risk of suicide in patients over 24. Tr.1681:25-1682:3, 1683:25-1684:4; A40, . That is irrelevant. "The only relevant issue is whether the prescribing physician was aware of the risks." *Wooten v. Johnson & Johnson Prods., Inc.*, 635 F. Supp. 799, 803 (N.D. Ill. 1986). Sachman testified repeatedly and unequivocally that he knew of paroxetine's risks, understood those risks extended to *all* patients, and warned Dolin and plaintiff of those risks over and over again. Tr.1737:13-1740:2, 1751:13-17, 1753:15-1754:2,

1779:17-23, 1803:7-19, 1805:9-23. His testimony shows that GSK had no further duty as a matter of law, and no reasonable jury could find otherwise. Indeed, the verdict here does not suggest otherwise; the district court declined to instruct the jury that GSK had no duty to inform Sachman of risks he already knew about. *Compare* R.466-1 at 13-16 (proposed instructions) *with* R.571 at 20 (instructions given).

2. Paxil's Labeling Did Not Cause Dolin's Suicide

The fact that Sachman knew of paroxetine's alleged risks and actually warned Dolin also breaks the chain of causation. "[T]he causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004). An informed prescribing decision "constitutes an intervening act that breaks the chain of causation between [the] inadequate warning and the injury suffered." *In re Zyprexa Prods. Liab. Litig.*, 2009 WL 2487305, at *14-15 (E.D.N.Y. July 27, 2009). Because Sachman knew—and actually warned Dolin—of the risks plaintiff claims were absent from Paxil's labeling, no reasonable jury could find that the labeling's alleged inadequacies caused Dolin's suicide.

The district court relied on Sachman's testimony that "if it was clear that this drug had a higher risk of causing suicide in the age group Stewart Dolin was in, [he] would have never prescribed it." Tr.1847:5-7; *see* A40. But no reasonable jury

could credit this conclusory, hypothetical statement given Sachman's repeated factual testimony that he actually believed that paroxetine's risks extended to patients over 24, warned of that risk, and still prescribed the drug. *Andersen v. City of Bessemer City*, 470 U.S. 564, 575 (1985) (clear error for factfinder to rely on testimony "so internally inconsistent … that a reasonable factfinder would not credit it"); *Bank of Ill. v. Allied Signal Safety Restraint Sys.*, 75 F.3d 1162, 1171-72 (7th Cir. 1996) ("inherent[ly] inconsisten[t]" testimony insufficient to raise question of fact on summary judgment).

Sachman admitted, moreover, that GSK provided him with the very information he claimed would be dispositive. Sachman testified that, had he been aware of the data in GSK's April 2006 briefing document, he would not have prescribed Dolin paroxetine. Tr.1759:20-1760:9. Yet Sachman confirmed that, in fact, he had received and reviewed GSK's May 2006 letter and attached labeling, which Sachman admitted contained the "exact same figures," describing the "same data set" using "the very same language" as the briefing document. Tr.1760:18-1761:4, 1764:5-13, 1764:25-1765:1-17; *compare* R.589-78 at 6, *with* R.589-4 at 1, 4.

Sachman also conceded that GSK never told him to disregard the information in the May 2006 letter and labeling. Tr.1765:18-22. Indeed, he did not know that the adult-suicidality warning in the 2006 labeling had been removed at FDA's insistence until after Dolin's suicide. Tr.1828:6-1829:3. When asked why he continued to prescribe Dolin paroxetine despite the May 2006 letter and attached labeling—which contained the information Sachman testified would have caused

him to stop prescribing paroxetine—Sachman explained: "[Dolin] had already been on [paroxetine]. I would not take a patient off a drug he was doing well on because of a label." Tr.1770:12-19. No reasonable jury could find that Sachman would have changed his prescribing decision had FDA permitted GSK to alter Paxil's labeling.

CONCLUSION

The judgment below should be reversed.

Dated: January 22, 2018

Respectfully submitted,

s/ *Lisa S. Blatt*
Lisa S. Blatt
Elisabeth S. Theodore
William C. Perdue
Stephen K. Wirth
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., N.W.
Washington, DC 20001
(202) 942-5000
lisa.blatt@apks.com

Andrew T. Bayman
Todd P. Davis
Heather M. Howard
KING & SPALDING LLP
1180 Peachtree Street, N.E.
Atlanta, GA 30309

Alan S. Gilbert
DENTONS US LLP
232 S. Wacker Drive, Suite 5900
Chicago, IL 60606

Counsel for GlaxoSmithKline LLC

CERTIFICATE OF COMPLIANCE

The foregoing brief complies with the type-volume limitation of Circuit Rule 32(c). The brief contains 13,998 words, excluding those parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) and Circuit Rule 32(b) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 2010 in New Century Schoolbook 12-point font.

s/ *Lisa S. Blatt*
Lisa S. Blatt

CERTIFICATE OF FILING AND SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I hereby certify that on January 22, 2018, I electronically filed the foregoing Brief of Appellant via ECF, and service was accomplished on counsel of record by that means.

s/ *Lisa S. Blatt*
Lisa S. Blatt

APPENDIX

CERTIFICATE OF COMPLIANCE WITH CIRCUIT RULE 30

I hereby certify that the Appendix herein includes all of the materials required by Circuit Rule 30(a) and (b).

s/ *Lisa S. Blatt*
Lisa S. Blatt

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WENDY DOLIN, Individually and as Independent Executor of the ESTATE OF STEWART DOLIN, deceased,

Plaintiff,

v.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation; and MYLAN INC., a Pennsylvania Corporation,

Defendants.

No. 12 C 6403
Judge James B. Zagel

MEMORANDUM OPINION AND ORDER

Plaintiff Wendy B. Dolin has brought this wrongful death action for damages and injunctive relief against defendants SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK") and Mylan, Inc. GSK now moves for summary judgment pursuant to Fed.R.Civ.P. 56(c), and Mylan moves to dismiss pursuant to Fed.R.Civ.P. 12(b)(6). For the following reasons, GSK's motion for summary judgment is granted in part and denied in part. Mylan's motion to dismiss is granted.

BACKGROUND

Plaintiff Wendy Dolin was married to Stewart Dolin for 35 years. According to the complaint, the Dolins were financially secure, owned their home outright, and had no pressing debts.

In June 2010, Mr. Dolin's family doctor wrote him a prescription for Paxil to treat work-

related anxiety and depression. Paxil is the name-brand version of the drug paroxetine hydrochloride ("paroxetine") and is owned and manufactured by GSK. The drug was first approved for use in the United States in 1992 for treatment of depression in adults.

Mr. Dolin's prescription, however, was ultimately filled with a generic version of paroxetine. Mylan obtained approval to market generic paroxetine in 2007. It is undisputed that the paroxetine Mr. Dolin ultimately ingested was manufactured by Mylan.

On July 15, 2010, six days after beginning to take paroxetine, Mr. Dolin left his office shortly after having returned from lunch with a business associate. He walked to a nearby Chicago Transit Authority Blue Line station at Washington and Dearborn in downtown Chicago. As a northbound train approached the station, Mr. Dolin leaped in front of it to his death. Blood tests taken with Mr. Dolin's autopsy were positive for paroxetine.

The complaint asserts that paroxetine and other similar serotonergic antidepressants called selective serotonin reuptake inhibitors ("SSRIs") can cause an adverse reaction called akathisia, a neurobiological phenomenon marked by profound inner restlessness and agitation. Patients experiencing such a reaction will often exhibit an inability to sit still, pacing and hand-wringing. The complaint asserts that akathisia has long been associated with suicidal behavior.

According to the complaint, Mr. Dolin exhibited classic symptoms of akathisia immediately before his death. A nurse alleged to have been on the platform at the same time as Mr. Dolin noticed that Mr. Dolin was "very agitated, pacing back and forth and looking down the tracks."

The paroxetine label in existence at the time of Mr. Dolin's death, however, did not warn of the drug's association with increased risk of suicidal behavior in adults. Indeed, the label stated that the suicidality risk did not extend beyond the age of 24. Plaintiff asserts that GSK

nevertheless had knowledge that paroxetine use carried a 6.7 times greater risk of suicidal behavior in adults compared to a placebo. Plaintiff asserts that GSK has been aware of paroxetine's association with this increased risk for over 20 years. Plaintiff asserts that GSK concealed the risk, however, and promoted its version of paroxetine, Paxil, as safe and effective.

Plaintiff also alleges that GSK was at least negligent in its manipulation of adverse event data such that the true risk associated with taking paroxetine was obscured. According to the complaint, in GSK's presentation of data on suicidal behavior in patients taking either paroxetine, a placebo, or a comparator drug, GSK included suicide attempts by placebo patients that had taken place before the clinical trial had actually begun. Including these attempts, Plaintiff asserts, yielded a misleading ratio of suicide attempts by paroxetine patients to suicide attempts by placebo patients. The implication is that the connection between paroxetine and suicide attempts was stronger than GSK made it appear.

As to Mylan, Plaintiff asserts that it was aware, or should have been aware, of this undisclosed connection between paroxetine and suicidal behavior, and the misrepresentation of the data supporting it. Nonetheless, Mylan continued manufacturing and selling generic paroxetine without notifying the medical community of the risk associated with its product.

Plaintiff has brought common law negligence and negligent misrepresentation claims as well as product liability claims under theories of both negligence and strict liability against both defendants. In its motion for summary judgment, GSK relies primarily on the argument that, because GSK did not manufacture the pill that Mr. Dolin actually ingested, it is entitled to judgment as a matter of law. Mylan, for its part, argues that Plaintiff's claims as to Mylan are preempted by federal law and must be dismissed.

DISCUSSION

I. GSK's MOTION FOR SUMMARY JUDGMENT

A. Summary Judgment Standard

Summary judgment should be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). A genuine issue of triable fact exists only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Pugh v. City of Attica, Ind., 259 F.3d 619, 625 (7th Cir.2001) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)).

B. The Hatch-Waxman Act

The tension between the unique federal regulatory scheme governing prescription drugs on the one hand, and Illinois state tort law on the other, is at the heart of the matter currently before the Court. Federal law requires approval from the U.S. Food and Drug Administration ("FDA") before bringing any new drug to market. Approval may be obtained only by filing a New-Drug Application ("NDA") with the FDA. The NDA process is both lengthy and expensive.

In 1984, in an effort to make generic versions of name-brand drugs more widely, safely, and inexpensively available, Congress passed the Drug Price Competition and Patent Term Restoration Act, also commonly known as the Hatch-Waxman Act ("the Act"). The Act provides for an expedited, less costly approval process for generic versions of drugs whose name-brand predecessors have already obtained FDA approval. Once the name-brand manufacturer's patent expires, generic manufacturers are able to enter the market with the benefit

of a far more streamlined approval process. This generic drug application process is referred to as the Abbreviated New Drug Application ("ANDA").

One caveat of this approach, however, is that the generic drug's design and warning label must identically match that of the name-brand version of the drug in all material respects. As the Supreme Court recently summarized:

> First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Second, a proposed generic must be "bioequivalent" to an approved brand-name drug. § 355(j)(2)(A)(iv). That is, it must have the same "rate and extent of absorption" as the brand-name drug. § 355(j)(8)(B). Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." § 355(j)(2)(A)(v).

Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S.Ct. 2466, 2471 (2013).

Once an NDA or ANDA has been approved, the manufacturer is prohibited from making any material changes to the drug's design. 21 C.F.R. § 314.70(b). Further, generic manufacturers (though, significantly, not name-brand manufacturers) are also prohibited from making unilateral changes to the drug's warning label. *See* § 314.150(b)(10).

Notably, in an effort to ensure that these reduced barriers to competitors' entry into the marketplace did not stymie innovation, the Act also allows for the extension of the patent protection period to afford name-brand manufacturers a longer period of time to recoup their investment in successful drugs.

The tension between this regulatory scheme and state tort law came to a head in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). The plaintiffs in *Mensing* were prescribed Reglan, the name-brand iteration of metoclopramide, a drug commonly used to treat digestive tract problems. *Id*. at 2572-73. The plaintiffs asserted that their long-term use of the drug caused them to

develop tardive dyskinesia, a severe neurological disorder, and they alleged that the warning labels in connection with the drug inadequate. *Id*. at 2573.

Although the plaintiffs were prescribed Reglan, their respective pharmacists filled the prescriptions with the generic equivalent, consistent with their respective states' drug-substitution laws.[1] This would prove disastrous to their claim. The plaintiffs duly filed suit against the manufacturer of the pills they ingested, generic metoclopramide, claiming an inadequate warning label. The Supreme Court, however, found that the claim was preempted by federal law, specifically, the Hatch-Waxman Act. *Id*. at 2577-78.

Hatch-Waxman prohibits a generic manufacturer from unilaterally making changes to its drug's warning label. The Court concluded that, with respect to any alleged defects in connection with a generic drug's warning label, a generic manufacturer's hands are simply tied. "If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id*. at 2578. Federal law preempted the plaintiffs' claim.

Two years earlier, the Court had found the same did not hold true for name-brand manufacturers. In *Wyeth, Inc. v. Levine*, 555 U.S. 555 (2009), the plaintiff claimed that a name-brand manufacturer was negligent in connection with a warning label, and the Court found that the discretion afforded name-brand manufacturers under the Act avoided any preemption problem. *See id*. at 581. Hatch-Waxman allowed name-brand manufacturers the latitude necessary to make changes to the label and satisfy their state tort law duties.

Crucial to *Levine* is the fact that the plaintiff ingested the name-brand version of the drug. The name-brand manufacturer sued by the plaintiff actually manufactured the pill ingested by the plaintiff. As in *Levine*, the name-brand manufacturer of the drug is sued here, but Mr. Dolin indisputably ingested a generic version of the drug. What legal recourse a plaintiff has under

[1] *See* 225 ILCS 85/25 for the analog in Illinois.

such circumstances appears to be a question of first impression in Illinois and in the Seventh Circuit.[2]

C. Plaintiff's Common Law Negligence Claims

1. *Common Law Negligence or Products Liability?*

At the threshold, GSK argues that Plaintiff's common law negligence claims are de facto products liability claims, merely "disguised" as claims sounding in common law negligence. In GSK's view, bringing a products liability claim against GSK on these facts is a non-starter, because the "product" alleged to have caused the injury at issue was not manufactured by GSK. At least on the face of it, construing Plaintiff's common law negligence claims as product liability claims certainly would serve GSK's ends.

Is the Court compelled to accept GSK's construction of this plaintiff's claims? Some states statutorily define what constitutes a products liability claim. For example, Arkansas state law defines a products liability action as "*all actions* brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing packaging, or labeling of any product." A.C.A. § 16-116-102 (emphasis added); *see also, e.g.*, O.R.S. § 30.900. Were actions brought by Illinois plaintiffs similarly constrained, GSK's argument might find more purchase here. *Cf. Phelps v. Wyeth, Inc.*, 857 F.Supp.2d 1114, 1121 (D.Or. 2012). Yet while states like Arkansas have decreed by statute that an action brought for injury caused by the design or warning of a product is necessarily a "product liability action,"

[2] Background reading for those unfamiliar with this legal problem includes: *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (1st Dist. 2008); Victor E. Schwartz, Phil Goldberg, Cary Silverman, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm was Allegedly Caused by Generic Drugs has Severe Side Effects*, 81 Fordham L. Rev. 1835 (2013); Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123 (2011).

Illinois has not.[3]

Nothing in Illinois common law compels a court to construe Plaintiff's common law negligence claims as product liability claims either. The injury here did indeed occur in connection with a product. And GSK manufactures products. Yet Plaintiff has not brought suit against GSK for tortious conduct committed strictly as a manufacturer of products. And, though GSK implicitly urges to the contrary, I see no reason why all suits brought against GSK must be brought against GSK *qua* manufacturer.

In addition to manufacturing one particular version of paroxetine (Paxil), GSK was responsible for paroxetine's design and warning label. And GSK vigorously contends that the design and warning label are not in themselves "products." GSK has not shown why Plaintiff should be precluded from claiming at common law that GSK, independent of its capacity as a manufacturer of one particular iteration of paroxetine, was negligent in connection with its responsibility for these "non-products," and that this negligence contributed to her injury.[4]

Having concluded that there is nothing fundamentally improper about analyzing Plaintiff's common law negligence claims as such, the inquiry turns to whether Plaintiff's complaint is sufficient to withstand GSK's motion for summary judgment.

2. *Negligence Analysis*

To claim common law negligence, a plaintiff must allege facts establishing a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by the breach. *Simpkins v. CSX Transportation, Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012). Whether a

[3] A 1995 amendment to the Illinois Code of Civil Procedure endeavored to establish a definition of product liability actions similar to that found in Arkansas and other states. The amended statute was subsequently held unconstitutional in its entirety, however, and no revised version has been enacted since. *See* 735 ILCS 5/2-201; *see also Best v. Taylor Machine Works*, 179 Ill.2d 367, 467 (Ill. 1997); *Whelchel v. Briggs & Stratton Corp.*, 850 F.Supp.2d 926, 932, n. 4 (N.D.Ill. 2012) (briefly describing the legislative history and noting that courts must analyze a defendant's argument under the version of the statute that existed prior to the ill-fated 1995 amendments).
[4] *See also* section I.C.3.ii, *infra*.

duty exists is a question of law for the court to decide. *Id*.

In Illinois, "the touchstone of [a] court's duty analysis is to ask whether a plaintiff and a defendant stood in such a relationship to one another that the law imposed upon the defendant an obligation of reasonable conduct for the benefit of the plaintiff." *Id*. at 1097. Significantly, however, whether a duty exists "does not depend upon contract, privity of interest, or the proximity of relationship, but extends to remote and unknown persons." *Id*. There need not be a direct relationship between the parties. *Id*. Rather, "[t]he 'relationship' referred to in this context acts as a shorthand description for the sum of four factors:

> (1) the reasonable foreseeability of the injury;
> (2) the likelihood of the injury;
> (3) the magnitude of the burden of guarding against the injury; and
> (4) the consequences of placing that burden on the defendant."

Id.

So on the one hand, a duty does not depend on the proximity of relationship and extends to remote and unknown persons. On the other hand, the Illinois Supreme Court has also made clear that there is no "duty to the world at large." *Id*. The sum of these four factors, referred to as the "relationship" between the parties, is the limiting principle that allows for the former but stops short of the latter. *See id*.

Numerous courts outside of Illinois and the Seventh Circuit take a dim view of the notion that a name-brand defendant such as GSK might owe a duty of care to a consumer of the generic version of one of its drugs. *See Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994); *see also Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613-14 (8th Cir. 2009); *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 882 F.Supp.2d 1020, 1029-30 (W.D.Tenn. 2012); *Phelps*, 857 F.Supp.2d at 1121; *Metz v. Wyeth LLC*, 830 F.Supp.2d 1291, 1293 (M.D.Fla. 2011) (collecting cases); *but see Conte v. Wyeth, Inc.*, 168 Cal.

App. 4th 89 (1st Dist. 2008). These judges may well be right, but I am not yet ready to join their opinions.

Plaintiff has alleged that GSK was at least negligent in connection with paroxetine's design and warning label. Construing all facts in Plaintiff's favor for purposes of this motion, *see Srail v. Village of Lisle, Ill.*, 588 F.3d 940, 948 (7th Cir. 2009), the foreseeability of Plaintiff's injury as a result of such negligence should not be controversial. First, once GSK's patent protection for paroxetine expired, it was no surprise that another manufacturer would begin producing a generic version of the drug, and that consumers in the market for Paxil would begin purchasing it.[5] And it was well understood that any generic manufacturer would be required by law to use GSK's design and warning label, and that any defects later discovered could only be cured by GSK. Under such circumstances, it was entirely foreseeable that negligence on the part of GSK with respect to paroxetine's design and warning label could result in injury to a consumer ingesting a subsequent generic version of the drug.

Continuing with the duty inquiry described above, and again construing all facts and drawing all reasonable inferences in Plaintiff's favor, GSK has not shown why the likelihood of injury was so remote as to undo GSK's duty of care. The principal distinction GSK insists upon – that Mr. Dolin did not ingest a product that GSK manufactured – does not lessen the likelihood that GSK's allegedly tortious conduct would lead to Plaintiff's injury. Under the regulatory scheme created by the Hatch-Waxman Act, whether a consumer ingests the name-brand or generic version of a given drug is immaterial as to the likelihood that negligence in the design or warning label of that drug will cause injury.

[5] Every state has now enacted drug substitution laws, requiring pharmacists under most circumstances to substitute available generic drugs for name-brand drugs when filling prescriptions. Schwartz, Goldberg, Silverman, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm was Allegedly Caused by Generic Drugs has Severe Side Effects*, 81 Fordham L. Rev. at 1847-48. On average, the generic version of a drug now seizes 80 percent of name-brand sales, up from 79 percent in 2010 and 63 percent in 2006. *Id.*

The third and fourth considerations, the magnitude of the burden of guarding against the injury, and the consequences of placing that burden on the defendant, are closely related. Guarding against the injury alleged here, however, could be as simple as updating the warning label. There may well be something to be said for "over-warning," and the problem of inadvertently deterring consumers from talking medication that would genuinely help them. But there is nothing yet in the record here to suggest that this problem is so grave as to warrant finding that GSK owed no duty of care to Plaintiff. And GSK does not make the argument.

That GSK did not manufacture the pill Mr. Dolin ingested is largely immaterial on this point. A problem with paroxetine's warning label and design will impact the name-brand version of the drug manufactured by GSK and any generic versions of the drug equally. The same "fix" will be required. GSK will not be tasked with the burden of crafting one new warning label for Paxil, and then other discrete warnings for various generic iterations of the drug – that all of the iterations of paroxetine are bio-equivalent and require the same warning is precisely the point. Further, GSK has been compensated for taking responsibility for paroxetine's design and warning label with an extended period of government-protected monopoly privileges in connection with the sale of its particular version of paroxetine, Paxil.

In sum, consideration of these four factors on this record leads to a conclusion that these parties stood in a relationship to one another that, while clearly not "direct," was sufficient for the law to impose a duty of reasonable conduct upon GSK for the benefit of Plaintiff. *See Simpkins*, 965 N.E.2d at 1097. With respect to breach, the complaint contains specific allegations regarding GSK's use of scientifically questionable methods to assess and report the presence of adverse side effects in connection paroxetine. It also sets forth specific allegations regarding GSK's failure to update paroxetine's warning label in 2007, despite having knowledge

of clinical studies apparently indicating that an update was called for. Plaintiff has raised a genuine issue of material fact as to whether GSK, through this and other allegedly negligent conduct, breached its duty, proximately causing Plaintiff's injury. [6]

3. *GSK's Counter-Argument: Mr. Dolin Did Not Ingest GSK's "Product"*

i. Did GSK Contribute to a Risk of Harm?

GSK argues that Plaintiff cannot even satisfy the threshold requirement that GSK must be shown to have created or contributed to a risk of harm to the plaintiff. *See id*. at 1098. "Because Mr. Dolin did not ingest GSK's product Paxil before his death," GSK asserts, "Paxil did not and could not cause his death." Def. Reply at 17. Yet while it is clear that GSK did not manufacture the version of paroxetine that Mr. Dolin ingested, GSK does more than simply manufacture its own version of the drug. And as noted above, GSK has offered no reason why it should be held liable only for those injuries caused by its negligence as a manufacturer.[7]

As the patent holder, GSK was responsible for paroxetine's design and warning label. Under the Hatch-Waxman Act, only GSK was legally permitted to cure any warning label defects. GSK is alleged to have been negligent with respect to paroxetine's design and warning label, and, if true, such negligence would necessarily contribute to a risk of harm to the consumers of any iteration of paroxetine, whether the name-brand version that GSK happens to manufacture, or another's company's generic version of the drug.

ii. Must GSK's "Product" Actually Have Caused the Injury?

GSK argues that, even if GSK did contribute to a risk of harm to the plaintiff, the

[6] GSK does little to refute these assertions or otherwise contest Plaintiff's claim on the merits, electing instead to rest almost entirely on the argument that consumers of generic drugs simply cannot bring claims for injury against the drug's name-brand manufacturer. I anticipate that a second motion for summary judgment, this one actually addressing the merits of the claim, will be forthcoming.

[7] As will be discussed in section I.D.2, *infra*, it is not clear that this reasoning applies with equal force in the strict liability context.

relationship between the parties is nevertheless too remote to impose a duty on GSK. "[I]n order to recover in a products liability action under Illinois law, regardless of the theory alleged, it is axiomatic that a plaintiff must show that the defendant's product *actually caused* the alleged injuries." Def. Brief in Support of MSJ, p. 13 (emphasis in original). "No duty is imposed upon a manufacturer that did not manufacture the product at issue." *Id*. at 18. And, "while a manufacturer owes a duty to plaintiffs who will use its drug…the duty is not so broad as to extend to anyone who uses the type of drug manufactured by a defendant." *Id*. (citing *Smith v. Eli Lilly & Co.*, 137 Ill.2d 222, 265 (Ill. 1990)).

This argument has a certain surface appeal, but on the facts claimed here, it suffers from two flaws.

First, as noted in section I.C.1, *supra*, I see no reason why all of Plaintiff's claims must be viewed and analyzed through the rubric of product liability law. GSK's position on this point is troubling in that it seeks to have things both ways. GSK vigorously contends that paroxetine's warning label and design are not products, and that GSK cannot, therefore, be held liable as their manufacturer. A reasonable argument can be made in support of that position. But it is something of an overreach when GSK *also* contends that alleging negligence on GSK's part in connection with the warning label and design must nevertheless be construed as a *product* liability claim – a product liability claim that Plaintiff cannot win because her husband did not ingest GSK's "product." *Cf. Chatman v. Pfizer, Inc.*, 2013 WL 1305506, *9 (S.D.Miss. March 28, 2013).

Another flaw in this argument is that it conflates two facially similar, but fundamentally distinct, tort liability problems. One is the problem actually at issue here. It arises when an injury occurs in connection with a given product, and a plaintiff asserts that tortious conduct by

someone other than the product's manufacturer caused or contributed to the injury.[8]

The other is the distinct problem of indeterminate tortfeasors. This arises when a plaintiff is injured by a product, but is unsure as to which manufacturer among the numerous manufacturers of similar products was responsible for the particular product with which the plaintiff came into contact.

Illinois Courts have taken a dim view of claims burdened by this latter difficulty. As GSK notes, a manufacturer cannot be held liable "without proof that the particular [manufacturer's] specific product caused the injury for which recovery is sought." *Lewis v. Lead Indus. Ass'n, Inc.*, Ill. App. 3d 95, 102-03 (1st Dist. 2003). And, "[t]he fact that over 300 companies sold a similar product for similar purposes cannot fairly be held to have created a sufficient nexus such that each company can be responsible for the injuries caused by others' products." *Smith*, 137 Ill.2d at 260.

Where a plaintiff is injured by a product, but is unable to identify the manufacturer responsible for the product, Illinois will not permit a claim brought against another manufacturer of a similar product. A manufacturer's duty is not "so broad as to extend to anyone who uses or might be injured by a like-kind product supplied by another." *Lewis*, Ill. App. 3d at 103. This is true, even where it can be shown that all of the manufacturers were similarly negligent. *See*

[8] *See* Madden & Owen on Products Liability, § 19:4 (collecting cases); Melissa Evans Bush, Products Liability and IP Licensors, 22 Wm Mitchell L Rev. 299, 311-14 (2000) (collecting cases). A review of cases of this type reveals that most involve a non-manufacturing defendant that is hired to perform some service in connection with the product, often developing its design. At least one Illinois Appellate Court has held that such defendants may be found liable for negligence, but that they may not be held strictly liable. *Mechanical Rubber & Supply Co. v. Caterpillar Tracker Co.*, 80 Ill. App.3d 262, 264 (3d. Dist. 1980); *see also* section I.D.2, *infra*.

The prescription drug scenario may be unique in this context, insofar as the name-brand company provides its design and warning label to the generic company, not voluntarily, but at the direction of the Hatch-Waxman Act. On the other hand, the Act does compensate the name-brand company for this "service" in the form of an extended period of government-protected monopoly control over the sale of the product. Further, that the name-brand company will be expected to provide this information is readily foreseeable, and the identity of the particular company that will make use of the information is readily ascertainable. Further still, the name-brand company maintains control over the design and warning label in accordance with the Act.

Smith, 137 Ill.2d at 266. Causation cannot be ignored. Each of the manufacturers may have been similarly negligent, but only one actually caused the plaintiff's injury, and the plaintiff must be able to identify *that* manufacturer in order to proceed with his or her claim. *See id*.

It is unclear, however, what work this line of reasoning does toward resolving the question actually before the Court.

Plaintiff here *can* identify the entity she alleges to have actually caused her injury. If Plaintiff were suing GSK for negligence in manufacturing its version of paroxetine when in fact it was the negligence of some other unknown paroxetine manufacturer that actually caused Plaintiff's injury, much of the product identification case law to which GSK cites may well have been controlling. But that is not the limited claim here. GSK is being sued for its alleged negligence in connection with paroxetine's design and warning label. GSK ultimately employed that design and label in Paxil, the version of paroxetine that GSK manufactures, but GSK has not shown why that is material in this context. The negligence here is extrinsic to the Paxil manufacturing process, and, if true, it could proximately cause injury to consumers of all versions of paroxetine, including the generic version that Mr. Dolin ingested.

Taken out of context, language in product identification cases like *Smith* and *Lewis* may well appear to support GSK's argument. In truth, the principles for which that line of cases stands are inapposite here.

iii. *Foster v. American Home Products Corp.*

It is difficult to criticize GSK for offering the "this was not our product" argument. It was presented stridently by the defendant name-brand manufacturer in the leading case dealing with this question, and, there, the Court accepted it. *See Foster*, 29 F.3d at 168; *Foster*, Brief for Appellee at 9-16. Numerous courts have subsequently cited *Foster* with approval. *See Smith*,

657 F.3d at 424; *Mensing*, 588 F.3d at 613-14; *Strayhorn*, 882 F.Supp.2d at 1029-30; *Phelps*, 857 F.Supp.2d at 1121; *Metz*, 830 F.Supp.2d at 1293 (collecting cases). Yet neither *Foster*, nor any of the courts relying on *Foster*, addressed the issue discussed above – whether a plaintiff injured by a product may assert that tortious conduct on the part of someone other than the product's manufacturer and extrinsic to the manufacturing process contributed to the injury.

As in this case, the *Foster* Court was asked whether a name-brand defendant stood in such a relationship with a consumer of a generic version of one of its products so as to owe that consumer a duty of care. *See Foster*, 29 F.3d at 171. The *Foster* Court held that there was "no such relationship" because the plaintiff was "injured by a product that [the defendant] did not manufacture." *Id*.

The *Foster* Court, as GSK urges here, analyzed the complaint as though it presented an indeterminate tortfeasor problem. *Compare Foster*, 29 F.3d at 168 (and cases cited) *with* GSK Reply, p. 12. Where a plaintiff is unsure as to the identity of the manufacturer that actually produced the injury-causing product, that plaintiff cannot simply bring suit against any manufacturer that produces similar products. *See Foster*, 29 F.3d at 168; *Lewis*, Ill. App. 3d at 102-03. A manufacturer is not liable for injuries caused by the products of other manufacturers. *See Foster*, 29 F.3d at 168; *Foster*, Brief for Appellee at 13.

Yet to suggest that the question actually raised here is simply whether GSK may be held liable for injuries caused by a product that Mylan manufactured is incomplete and misleading. The question is whether GSK, though not the pill's manufacturer, may nevertheless be held liable for tortious conduct that was extrinsic to the manufacturing process and that contributed to Plaintiff's injury. Plaintiff has not failed to identify the "true" manufacturer of the product in question. The claim is not brought against GSK in lieu of the company that actually

manufactured the pill Mr. Dolin ingested. The claim is brought against GSK because GSK – not Mylan – was actually responsible for the pill's design and warning label. *Smith*, *Lewis*, and the other cases relied upon by GSK and *Foster* undermine only the former type of claim. In my view, they are inapposite to the claim before the Court, and *Foster* is not persuasive here.

4. *Negligent Misrepresentation*

The foregoing duty analysis and conclusion apply with equal force to Plaintiff's negligent misrepresentation claim. To state a claim for negligent misrepresentation, a plaintiff must show: (1) a false statement of material fact; (2) negligence on the part of the defendant in ascertaining the truth; (3) intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statements; and (5) damage to the other party resulting from such reliance. *See Board of Educ. of City of Chicago v. A,C and S, Inc.*, 131 Ill.2d 428, 452 (Ill. 1989).

I find that Plaintiff's case with respect to these elements is sufficient to survive GSK's motion for judgment.

GSK asserts that Plaintiff cannot show that GSK intended to induce Mr. Dolin to act. It "belies common sense," GSK contends, to argue that GSK intended to induce Mr. Dolin to purchase one of GSK's competitor's products. This argument simply manipulates what is little more than a level of abstraction problem. Given GSK's version of paroxetine and a competitor's version of paroxetine, there is no doubt that GSK would want consumers to purchase GSK's version, Paxil. And, indeed, Mr. Dolin's physician prescribed Paxil for him.

Taking a slightly broader view, however, it is certain that GSK intended for consumers to trust that paroxetine was a safe and effective drug. For consumers to believe otherwise would be adverse to GSK's interests. Consistent with Illinois generic drug substitution law, Mr. Dolin's prescription was ultimately filled with the generic equivalent to Paxil. But GSK's interests with

respect to general public acceptance of the safety of all paroxetine is, in my view, sufficient to undermine GSK's argument that they did not intend to induce Mr. Dolin to act.

GSK next argues that Plaintiff cannot satisfy the reliance requirement because Plaintiff alleges that misrepresentations were made only to Mr. Dolin's physician and not directly to Mr. Dolin. This turns principles undergirding the learned intermediary doctrine on their head. First, the complaint does allege that GSK's misrepresentations were made to Mr. Dolin. Complaint ¶124. But it is in any event clear that GSK knew the information would be used and relied upon by physicians, and that the expertise of these learned intermediaries would then be relied upon by patients. Unsurprisingly, that is what is alleged to have happened here. *Cf. Quinn v. McGraw-Hill Companies, Inc.*, 168 F.3d 331, 335 (7th Cir. 1999); *Smith v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 886 F.Supp.2d 911, 927-28 (S.D.Ill. 2012).

GSK urges essentially the same arguments in opposition to Plaintiff's fraud-based claims.[9] They are similarly lacking in merit. The complaint demonstrates genuine issues of material fact in connection with these claims as well, and it is sufficient to withstand GSK's summary judgment motion.

D. Plaintiff's Product Liability Claims

A product liability claim may be brought under a theory of negligence, or a theory of strict liability. *Blue v. Environmental Engineering, Inc.*, 215 Ill.2d 78, 89 (Ill. 2005). "Illinois cases considering a cause of action for defective products liability sounding in negligence rather than strict liability are rare, probably because it appears to plaintiffs that it is easier to prove the strict liability count." *Id.* at 95 (noting that this is certainly true when speaking of a manufacturing defect, but that a design defect claim is more akin to a negligence claim).

For a plaintiff to prevail under either theory, the product must be shown to be

[9] *See* note 6 and accompanying text.

unreasonably dangerous. *See Mikolajczyk v. Ford Motor Co.*, 231 Ill.2d 516, 525 (Ill. 2008) (as to strict liability); *Calles v. Scripto-Tokai Corp.*, 224 Ill.2d 247, 270-71 (Ill. 2007) (as to negligence). Generally, there are three ways a product alleged to have caused injury may be found to be defective and thus unreasonably dangerous. The product may contain a manufacturing defect, it may be defective in design, or it may be rendered defective due to inadequate instructions or warnings. *Blue*, 215 Ill.2d at 93.

Whether a product is defective is ordinarily a question of fact for the jury to decide. *Korando v. Uniroyal Goodrich Tire Co.*, 159 Ill.2d 335, 344 (Ill. 1994). Here, Plaintiff asserts that the pill ingested by Mr. Dolin was defective by virtue of its design and by virtue of an inadequate warning label.

1. *Products Liability – Negligence Theory*

In Illinois, a product liability action asserting a claim that is based on negligence falls within the framework of common law negligence. *Calles*, 224 Ill.2d at 270. One might then ask what work is done by distinguishing a given common law negligence claim as a "product liability claim based on negligence." In my view, recognizing the distinction contributes little to the analysis.

The only material difference appears to be that the duty analysis in a "product liability claim based on negligence" is short-circuited with a presumption. That is, it is presumed that a "manufacturer has a non-delegable duty to design reasonably safe products." *Id.*

This "product liability based" understanding of duty presents something of an awkward fit for Plaintiff here. As GSK emphasizes, it is the "manufacturer" that owes a duty to design reasonably safe products. And GSK did not manufacture the pill that Mr. Dolin ingested. This apparent tension could be reconciled by adopting a more expansive understanding of what it is to

be a "manufacturer" for purposes of the duty analysis.[10] In my view, however, the more sensible analysis simply concludes that such claims exist outside of the product liability framework.[11]

In any event, the practical impact of this distinction on the viability of Plaintiff's negligence claim is minimal. Whether it is understood to be inside or outside the rubric of products liability, the claim and analysis still fall within the framework of common law negligence, and the same elements must be pled and proved. *See Calles*, 224 Ill.2d at 270. The only difference is that, understood as a claim outside the rubric of products liability, Plaintiff must actually contend with the duty element, rather than benefit from the presumed duty manufacturers owe to consumers of their products.[12]

As discussed in section I.C.2, *supra*, I find that, under the complaint's allegations, GSK did indeed owe a duty of care to Plaintiff. This conclusion arises from a duty analysis under Illinois common law. With respect to Plaintiff's negligence claims, then, whether GSK is a "manufacturer" in the context of this case and for purposes of the duty owed by manufacturers to design reasonably safe products is immaterial. So too is any effort to distinguish Plaintiff's common law negligence claims as product liability claims, insofar as they are product liability claims brought on a theory of negligence.

2. *Product Liability – Strict Liability Theory*

Plaintiff's product liability claims brought under a theory of strict liability encounter greater obstacles. Under a strict liability theory, a plaintiff may prevail on a product liability claim without showing fault on the part of the defendant. *See Calles*, 224 Ill.2d at 270. In the absence of the burden to show fault however, a strict product liability claim must satisfy other criteria.

[10] *See* section I.D.2, *infra*.
[11] *See* sections I.C.1, *supra*.
[12] *See* section I.C.2, *supra*.

To recover in a product liability action under strict liability in Illinois, a plaintiff must plead and prove that the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control. *Mikolajczyk v. Ford Motor Co.*, 231 Ill.2d 516, 525 (Ill. 2008). Strict liability for injuries resulting from a defective product may be found against persons in the "distributive chain," including manufacturers, suppliers, distributors, wholesalers and retailers. *See Hammond v. North American Asbestos Corp.*, 97 Ill.2d 195, 206 (Ill. 1983).

Again, a product may be found to be defective and thus unreasonably dangerous by virtue of a manufacturing defect, a design defect, or an inadequate warning. Under the Hatch-Waxman Act, however, the company responsible for a given product's design and warning is not necessarily the manufacturer and does not necessarily fall anywhere within the distributive chain.[13]

And there lies the difficulty for this plaintiff and others similarly situated. A theory of product liability law that holds strictly liable only manufacturers and companies within the product's distributive chain cannot easily accommodate a regulatory scheme that severs the responsibility for manufacturing and distributing the product from the responsibility for its design and attendant warning, assigning the former to one company, and the latter to another.

Under the Act, whether Mr. Dolin ingested a generic version of paroxetine or the name-brand version of paroxetine, GSK had control over its design and warning. And yet GSK only manufactured, and under Illinois product liability law apparently can only be held strictly liable for, the name-brand version.

In an effort to reconcile this inherent tension a court might simply adopt a more expansive view of product liability law. For example, and as Plaintiff urges, one might conceive

[13] *See* section I.B, *supra*.

of the drug's design or its warning label as the "product" that is actually at issue here. Such an understanding would put GSK in the chain of production, regardless of which version of paroxetine Mr. Dolin actually consumed. In my view, however, clear policy concerns undergirding the doctrine of strict product liability counsel against so expansive an understanding of the law.

Strict product liability acknowledges that products will sometimes cause injury, even in the absence of fault. Holding manufacturers and others in the chain of distribution liable for these faultless injuries reflects a policy decision to burden sellers, rather than consumers, with this risk.

> [P]ublic policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

Restatement (Second) of Torts § 402A, Comment *c* (1965).

In the case of prescription drugs, when a brand-name manufacturer's patent expires, and another company begins manufacturing a generic version of the drug, the availability and use of the drug generally will expand dramatically. Indeed, this was one of the Hatch-Waxman Act's principal aims. To the extent use of the drug comes with a risk of injury, however, this increase in use comes with a correlative increase in exposure to that risk.

But to hold a name-brand manufacturer strictly liable for injuries caused by a drug's defective design or warning when a *generic* version of the drug is purchased and ingested is not to treat the injury "as a cost of production," or to allocate the cost to "those who market the products." *See* Restatement (Second) of Torts § 402A, Comment *c* (1965). The name-brand manufacturer is outside the chain of distribution and does not benefit from the sale of the generic

version of the drug. To hold the name-brand manufacturer liable for injuries caused by a defective design or warning when a generic version of the drug was ingested is to treat the injuries as a cost of production of the *name-brand* version of the drug.

To be sure, a name-brand manufacturer could account for this cost by raising the price it charges for the name-brand drug. And it is also reasonable to note, as does Plaintiff, that Hatch-Waxman compensates name-brand manufacturers for the mandated sharing of their designs and warning labels with competitors in the form of a more lengthy period of government-protected monopoly control over their products. But these points do not persuade me that holding a name-brand manufacturer strictly liable for an injury resulting from contact with a generic version of the drug is consistent with the policies underlying strict liability theory.

First, a quite substantial portion of name-brand sales naturally occurs prior to the expiration of the name-brand manufacturer's patent protection – that is, before a generic manufacturer has even entered the market. Raising prices in an effort to account for the total cost of injuries that will result when unknown future generic manufacturers enter the market and bring an unknown and possibly incalculable increase in the drug's availability and use hardly seems plausible.

Second, and in any event, strict product liability theory anticipates that, as increasing sales increase a manufacturer's exposure to the risk that the use of its product will actually lead to injury, there will be a proportionate increase in earnings over which to spread the cost of those injuries. The rationale for holding manufacturers responsible for the cost of accidental injuries caused by their products is that those who market the products are the "proper persons to afford it." Here, the name-brand manufacturer sees no proportionate increase in earnings commensurate with the increased risk exposure. In my view, to hold a name-brand manufacturer

strictly liable under such circumstances is at odds with policy underlying strict liability theory.

This reasoning does not hold where a name-brand manufacturer is found, not strictly liable, but liable for negligence. An injury (or at least liability for an injury) that occurs due to negligence can be avoided simply by satisfying one's duty of care. Significantly, this is so without regard to whether the name-brand or generic version of the drug was consumed. Where a company's negligence in connection with a product causes injury, it may naturally be held liable for having caused that injury. Where there is no fault, however, the public policy rationale that justifies burdening the seller with the cost of injury rather than the consumer does not merit placing liability on an entity whose benefit from the sale is so remote, and whose ability to account for the cost is so limited.

II. MYLAN's MOTION TO DISMISS

On June 24, 2013 the United States Supreme Court issued its decision in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013), a case which appears to control the claim Plaintiff has brought against Mylan, the company that manufactured the generic paroxetine that Mr. Dolin actually ingested. In *Bartlett*, the Court held that state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under *Mensing*. *Bartlett*, 133 S.Ct. at 2471. In light of the Court's holdings in *Bartlett* and *Mensing*, Plaintiff now concedes that her claims against Mylan alleging that Mylan failed to make proper warnings or to make design changes are preempted by federal law and must fail.

Plaintiff maintains, however, that her claim that Mylan breached its duty by failing to issue "Dear Doctor" letters to physicians with updates as to the "true" nature of the risks associated with paroxetine remains viable. I disagree.

It is true that, consistent with *Mensing*, generic manufacturers are permitted to send such

letters to physicians containing important information about drugs, so long as the content of the letters is "consistent with and not contrary to" the drug's approved labeling. *PLIVA*, 131 S.Ct. at 2576. Plaintiff argues that the "Dear Doctor" letter she would have had Mylan send would satisfy *Mensing*, but I do not see how that could be true.

Plaintiff alleges that Mylan knew that paroxetine's post-2007 label did not include any warning of the risk of adult suicidality, and further alleges that Mylan knew it should have contained such a warning. Plaintiff asserts that Mylan should have sent letters to physicians "indicating that paroxetine's adult suicidal behavior risk was higher than the class-wide risk contained in the label."

But Plaintiff does not explain (and I do not see) why such a letter would not be inconsistent with and contrary to paroxetine's approved warning label. The message Plaintiff seeks to have had communicated is that paroxetine's approved warning label was inaccurate and misleading: "contrary" to the approved label, there is indeed an increased risk of suicidality for adults. These "Dear Doctor" letters are considered "labeling" under FDA regulations, and Mylan, as a generic manufacturer, was prohibited from making any such labeling changes by the FDA. *See PLIVA*, 131 S.Ct. at 2576. A claim that would have a generic defendant make such changes is thus preempted by federal law. *See Bartlett*, 133 S.Ct. at 2466; *PLIVA*, 131 S.Ct. at 2576.

CONCLUSION

For the foregoing reasons, defendant GSK's motion for summary judgment is granted as to Plaintiff's claim arising under strict liability. GSK's motion for summary judgment is denied as to the remainder of Plaintiff's claims. Mylan's motion to dismiss is granted.

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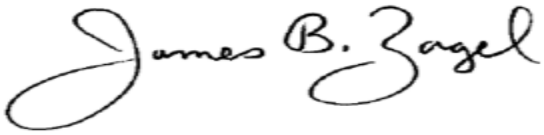

James B. Zagel
United States District Judge

DATE: February 28, 2014

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WENDY B. DOLIN, Individually and as Independent Executor of the ESTATE OF STEWART DOLIN, Deceased,

Plaintiff,

v.

SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, A Pennsylvania Corporation,

Defendant.

No. 12 C 6403
Judge James B. Zagel

MEMORANDUM OPINION AND ORDER

Plaintiff Wendy Dolin brings this action against Defendant SmithKline Beecham Corp. d/b/a GlaxoSmithKline ("GSK"). Plaintiff's husband, Stewart Dolin ("Mr. Dolin"), was fifty-seven years old when he committed suicide in July 2010 after being prescribed and ingesting a generic form of the drug Paxil—GSK's trade name for paroxetine hydrochloride.

This matter is presently before me on two motions for summary judgment filed by GSK. GSK's first motion argues that Plaintiff's state-law claims are preempted by federal law while its other motion contends that there are no genuine issues of material fact. For the following reasons, I am denying both motions in their entirety.

GSK's argument for "implied conflict preemption" has been uniformly rejected every time it has been brought within the Seventh Circuit. *See Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010) (failure to warn claims involving Paxil-induced suicide of a 23-year-old woman not preempted by federal law); *Forst v. Smithkline Beecham Corp.*, 639 F. Supp. 2d 948, 953 (E.D. Wis. 2009) (failure to warn claims involving the Paxil-induced suicide

attempt of a 61-year-old man are not preempted by federal law); *Tucker v. SmithKline Beecham Corp*., 596 F. Supp. 2d 1225, 1227 (S.D. Ind. 2008) (failure to warn claims involving the Paxil-induced suicide attempt of a 55-year-old Catholic priest not preempted by federal law).

The Supreme Court has held that preemption is a demanding defense which will not succeed without "clear evidence" that the FDA would not have approved an enhanced warning to the drug's label. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). To meet this demanding burden, GSK is required to produce "clear evidence" that, had it added a Paxil-specific adult suicidality warning, that change would have been rejected by the FDA or deemed a misbranding of the drug.

GSK's preemption argument rests on the premise that the FDA has considered and rejected an adult suicide warning during the relevant time period, but the record demonstrates otherwise. On June 22, 2007, the FDA extended an invitation to GSK to discuss the option of keeping the 2006 Paxil-specific adult language in its current label by requesting a formal meeting. Specifically, the FDA told GSK: "If you would like to discuss this matter further [keeping the 2006 Paxil-specific adult warning in the Paxil label], please submit a formal meeting request." GSK, however, never asked for a formal meeting, nor did it seek additional labeling regarding Paxil-specific data. Moreover, GSK never sent a separate supplement and declined the FDA's invitation for a meeting to discuss the inclusion of the 2006 Paxil-specific adult warnings.

As the record currently stands, therefore, GSK has failed to meet its demanding burden of demonstrating by clear evidence that the FDA would have rejected a Paxil-specific adult suicide warning had GSK taken the FDA up on its request to schedule a formal meeting or submit a separate supplement to add the Paxil-specific adult suicide warnings.

GSK's other motion for summary judgment contains four distinct arguments. First, GSK argues that Plaintiff's claims fail because Mr. Dolin's prescriber, Dr. Sachman, knew that Paxil increased the risk of adult suicidal behavior prior to prescribing the drug to Mr. Dolin. Second, GSK argues that the Paxil label is adequate as a matter of law. Third, GSK argues that Plaintiff's claims based on misrepresentation and consumer fraud fail because, according to GSK, there is insufficient evidence of the element of reliance. And finally, GSK renews its previous motion for summary judgment based on the idea that GSK cannot be held liable here because Mr. Dolin ingested the generic form of Paxil and not the name-brand drug itself. None of these arguments are persuasive.

With regards to whether Dr. Sachman knew that Paxil increased the risks of adult suicidal behavior prior to prescribing the drug to Mr. Dolin and whether Dr. Sachman relied on the 2010 Paxil label in making his decision to prescribe Paxil to Mr. Dolin, the record does not support GSK's interpretation of Dr. Sachman's testimony. Considering the record in the light most favorable to the non-moving party, as I am required to do, Dr. Sachman's testimony suggests that (1) he did not know that Paxil increased the risk of suicidal behavior in adults over 24 prior to prescribing Paxil to Mr. Dolin in 2010, (2) he relied upon the 2010 Paxil label before prescribing Paxil to Mr. Dolin, (3) the 2010 Paxil label does not adequately warn about the risk of suicidal behavior beyond age 24, and (4) had he known of the risk, he would never have prescribed Paxil to Mr. Dolin. This is enough to defeat GSK's motion for summary judgment. Ultimately, these decisions cannot be made without assessing Dr. Sachman's credibility at trial.

Similarly, I cannot conclude at this point that GSK's 2010 Paxil label is adequate as a matter of law. Plaintiff is ready to offer multiple expert opinions on this matter, including Dr. Ross and Dr. Glenmullen. The adequacy of Paxil's 2010 label will depend on this testimony,

GSK's expert testimony, and the underlying statistical evidence. Reaching a decision before trial would be inappropriate.

GSK's final argument asks that I revise a previous decision of mine that was entered in a February 28, 2014 order. I assume the reader's familiarity with the facts and law set forth therein. Although I am allowed to change my previous decision on a renewed motion for summary judgment, there is nothing in the record that would justify doing so.

CONCLUSION

I am denying both of GSK's motions for summary judgment in their entirety.

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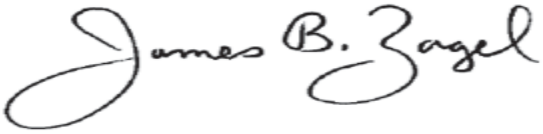


James B. Zagel
United States District Judge

DATE: February 11, 2016

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of Stewart Dolin, Deceased,	)	
Plaintiff,	)	
v.	)	No. 12 C 6403
GLAXOSMITHKLINE LLC,	)	
Defendant.	)	

OPINION AND ORDER

A jury returned a verdict in the amount of $3 million in damages in a wrongful death and survival action in favor of plaintiff Wendy Dolin, executor of the Estate of Stewart Dolin, deceased, and against defendant GlaxoSmithKline LLC ("GSK"). The case was initiated in the Circuit Court of Cook County, Illinois and removed to this court based on diversity of citizenship. A motion to remand to the state court was denied (Dkt. 73).[1] This court has jurisdiction pursuant to 28 U.S.C. §§ 1332 and 1441.

[1]SmithKlineBeecham Corporation, formerly a Pennsylvania corporation, converted into GlaxoSmithKline LLC, a limited liability membership company organized under Delaware law. The sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation, with its principal place of business in Wilmington, Delaware. Dismissed defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business in Pennsylvania. Defendant H.D. Smith Wholesale Drug Co., a Delaware corporation, with its principal place of business in Illinois, was dismissed as improperly joined. The amount involved exceeded $75,000.

The case is now before the court for ruling on the defendant's reserved motions for judgment as a matter of law or for a new trial.

Suit was brought to recover damages arising out of the death of plaintiff's husband, Stewart Dolin, a 57-year old attorney who was suffering from depression. He was prescribed and taking paroxetine, an antidepressant. Paroxetine is a drug designed, labeled and sold by GSK under the brand name Paxil. (The druggist who filled the prescription for paroxetine supplied a generic form of the drug produced and sold with the GSK Paxil label by Mylan Inc.) On July 15, 2010 Mr. Dolin left his office and went to a Chicago "L" train station and leapt in front of a train. Plaintiff alleges he was suffering from drug induced akathisia, a psychomotor agitation disorder.

The case went to trial on the claim that GSK negligently failed to include a warning in the label that the drug can be a cause of adult suicide despite being aware of a significant risk of suicide in adults taking the drug. It is alleged that GSK allowed an affirmative misrepresentation to exist in the label that there is no risk of suicide beyond the age of 24 years. The plaintiff also asserts that the label did not warn of akathisia's association with suicidal behavior. Plaintiff contends that GSK negligently misled the medical profession (including Mr. Dolin's physician and the Food and Drug Administration ("FDA")) by concealing and misrepresenting adult suicide risk data relating to paroxetine.

Prior Rulings

GSK moved for summary judgment three times. It first argued that because Mr. Dolin ingested a generic form of paroxetine it could not be liable for its conduct in creating and controlling the labeling used. The court disagreed. ***Dolin v. SmithKline Beecham Corp.,*** 62 F.

Supp. 3d 705, 713 (N.D. Ill. 2014) (Zagel, J.) (Dkt. 110) ("***Dolin I***"). GSK moved to have the ruling certified under 28 U.S.C. § 1292(b) for an interlocutory appeal. After that motion was denied GSK petitioned the United States Court of Appeals for the Seventh Circuit for a writ of mandamus to compel certification of an appeal. The petition was denied. ***In re GlaxoSmithKline LLC.***, 557 F. App'x 578, 579 (7th Cir. 2014).

GSK's second and third motions for summary judgment focused on Federal preemption as described in ***Wyeth v. Levine,*** 555 U. S. 555, 581 (2009). It argued that any state law claim was preempted because the FDA rejected its efforts to place certain warnings on the label. It was held that GSK failed to show that the FDA would have rejected a Paxil specific warning of the risk of adult suicide. In the third motion GSK urged that Mr. Dolin's physician was aware of the risks of adult suicide associated with the drug and that the label was adequate as a matter of law. Plaintiff's strict liability claims of design defect and failure to warn were dismissed. Negligence and consumer claims were allowed to proceed. ***Dolin v. Smith Kline Beecham Corp.,*** 2016 WL 537949 (N.D. Ill. Feb. 11, 2016) (Zagel, J.) (Dkt. 348) ("***Dolin III***").

In ***Mut. Pharm. Co., Inc. v. Bartlett***, 133 S. Ct. 2466 (2013) and in ***PLIVA v. Mensing,*** 131 S. Ct. 2567 (2011) the Supreme Court held that state-law label design defect claims that turn on the adequacy of label warnings are preempted by Federal law in the case of a generic supplier because a generic supplier has no power to change the label created by a brand-name supplier. *See* ***Bartlett,*** 133 S. Ct. at 2473; ***PLIVA,*** 131 S. Ct. at 2576. Accordingly, defendant Mylan Inc.'s motion to dismiss was granted. (Dkt. 110).

GSK's ***Daubert*** motions to exclude the testimony of plaintiff's expert witnesses (David Healy, M.D., David Ross, M.D., Ph.D., M.B.I. and Joseph Glenmullen, M.D.) were denied. 2015 WL 7351678 (N.D. Ill. Nov. 20, 2015) (Zagel, J.) ("***Dolin II")***.

The parties' motions *in limine* and objections to exhibits were resolved or reserved for ruling at trial. (Dkts. 465, 475, and 499.) Based on Rule 403 of the Federal Rules of Evidence, GSK's motion *in limine* to exclude any reference before the jury to criminal convictions of GSK for promoting Paxil in patients under age 18 and publishing misleading pediatric information with respect to Paxil was granted. The evidence in the case was limited to data dealing with adult suicide issues. Plaintiff was also precluded from offering studies showing minimal efficacy of paroxetine compared with placebo.

Shortly before trial plaintiff moved to amend her complaint to limit her claims to one count of negligence and one count of negligence with intent to injure. Negligence with intent to injure was ruled not to be a plausible claim. (Dkt. 490.) The case went to trial on the negligence claim only. Under Illinois law, plaintiff's burden of proof was to prove every essential element of her claim by a preponderance of the evidence.

The jury was instructed, in substance, as follows: GSK was responsible for the content of the paroxetine label. (21 C.F.R. § 201.80(e) and 121 Stat. 924-926.) GSK is charged both with crafting an adequate label and with ensuring that the warnings remain adequate as long as the drug is on the market. Under FDA regulations, GSK is required to revise and update its label to include a warning as soon as there is "reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved" (21 C.F.R. § 314.80(e)).

The jury was also told that FDA regulations permit a drug manufacturer to change a product label to add or strengthen a warning about its product without prior FDA approval so long as it later submits the revised warning to the FDA for review and approval (21 CFR §§ 314.70(c)(6)(iii)(A), (C)).

In recognition of the learned intermediary doctrine, the jury was told that GSK had a duty to warn only the prescribing physician of the risks of which it knew, or in the exercise of ordinary care, should have known.

Based on the rulings in ***Mason v. SmithKine Beecham Corp.,*** 596 F.3d 387 (7th Cir. 2010) and, more recently, ***In re (Fosamax Alendronate) Sodium Prods. Liab. Litig.,*** 852 F.3d 268 (3d Cir. 2017) the affirmative defense of Federal preemption as set forth in ***Wyeth v. Levine,*** 555 U.S. 555 (2009) was ruled to be a factual question for the jury. The court offered to submit the question to the jury with an appropriate burden of proof instruction. GSK took the position that preemption was a question of law for the court and declined to have its affirmative defense submitted to the jury in the form stated in the court's instructions.

Standards

Federal Rule of Civil Procedure 50(a) provides that if "a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party . . . the court may . . . grant a motion for judgment as a matter of law." For a renewed motion for judgment as a matter of law the standard is whether the evidence presented, combined with all reasonable inferences, is sufficient

to support the verdict when viewed in the light most favorable to the nonmovant. ***Dadian v. Vill. of Wilmette,*** 269 F.3d 831, 837 (7th Cir. 2001).

A new trial may be granted if the verdict is against the clear weight of the evidence or the trial was unfair to the moving party. ***Whitehead v. Bond***, 680 F.3d 919, 927 (7th Cir. 2012). When a motion for a new trial is based on a ruling of evidence, it must be shown that the error was such as to deny the party a fair trial. ***Perry v. Larson,*** 794 F.2d 279, 285 (7th Cir. 1986).

The Evidence

Paroxetine hydrochloride is a psychotropic drug of the Selective Serotonin Reuptake Inhibitor class ("SSRIs"). It is used, among other purposes, to treat major depressive disorders. The action of the drug on brain neurons is thought to be responsible for anti-depressant effects. Marketing of the drug began in 1992. Generic formulations have been available since 2003. The New Drug Application (NDA 20-031) was submitted in 1989 with data relating to suicides. In April 1991, the NDA was amended with a report containing data on suicides and suicide attempts. An approval letter for major depressive disorders (MDD) was issued on December 29, 1992. Paxil is not approved in the United States for any treatment in the pediatric population.

The testimony of all of the medical experts who testified reveals that it is recognized in the medical community that some patients treated with SSRIs may be more likely to attempt or commit suicide. An SSRI may activate patients with suicidal ideations or induce symptoms of emotional volatility leading them to attempt or commit suicide in order to escape intolerable feelings.

The so-called "black box" warning on the GSK label, the truth of which, in the case of Paxil, was a main focus of attention in this case (Joint Exhibit 1). Some content and the origin of the label is connected with criminal complaints against GSK by the Attorney General of New York in 2003 and later by United States Department of Justice resulting in a $3 billion fine against GSK for, among other things, withholding paroxetine data from the Food and Drug Administration ("the FDA") and unlawfully promoting the drug for pediatric (under age 18) uses.[2] The FDA conducted a pooled statistical analyses of SSRIs, including paroxetine, finding an increase in suicide and suicide ideation in pediatric cases treated with SSRIs. It then ordered that each SSRI have a standardized "black box" warning which, in the case of Paxil, provides as follows:

Suicidality and Antidepressant Drugs

> Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of PAXIL or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond the age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.)

[2] Based on Rule 403 of the Fed. R. Evid., the facts and results relating to the criminal actions and the results of related class actions against GSK were excluded from the evidence heard by the jury.

Another part of the GSK paroxetine/Paxil label which was a focus of attention in the evidence is the **WARNINGS** section:

WARNINGS

> **Clinical Worsening and Suicide Risk:** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond the age of 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older.
>
> The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4,400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1,000 patients treated) are provided in Table 1.

Table 1

Age Range	Drug-Placebo Difference in Number of Cases of Suicidality per 1,000 Patients Treated
Increases Compared to Placebo	
<18	14 additional cases
18-24	5 additional cases
Decreases Compared to Placebo	
25-64	1 fewer case
≥65	6 fewer cases

No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression.

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening of depression or suicidality, especially if those symptoms are severe, abrupt in onset, or were not part of the patients presenting symptoms.

> If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see PRECAUTIONS and DOSAGE AND ADMINISTRATION – Discontinuation of Treatment With PAXIL, for a description of the risks of discontinuation of PAXIL).
>
> **Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and non-psychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers.** Prescriptions for PAXIL should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

Mr. Dolin's attending physician, Dr. Martin Sachman, an internist, testified that he relied on the 2010 Paxil label in deciding to prescribe Paxil for the depression experienced by Mr. Dolin in June of 2010. He said that the label did not warn that the drug could induce suicidal behavior in adults over 24, rather that it stated the risk of suicide did not extend beyond age 24 and that he relied on those representations. It was his testimony that had the label warned of the risk of adult suicidal behavior in persons over the age of 24, he would not have prescribed the drug for Mr. Dolin. Dr. Sachman stated that he had other drug choices available for the treatment of Mr. Dolin's depression.

Plaintiff's experts, Dr. Healy and Dr. Ross, testified in support of Dr. Sachman's interpretation that the label did not warn of adult suicide risks. There was also testimony that the label did not warn that akathisia can lead to suicide.

Notwithstanding a vigorous cross-examination relating to the medical community's knowledge of adult suicide risks, the jury was entitled to accept Dr. Sachman's testimony that he

relied on the statement that the risk of adult suicide did not extend beyond the age of 24 when he prescribed paroxetine for Mr. Dolin.

It was plaintiff's position that the language in the Black Box and Warnings sections of the GSK label stating that "[s]hort-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond the age 24" was based on pooled analyses of 11 antidepressant drugs (SSRIs) not on Paxil data only. It was contended that the statement is not true of data relating only to paroxetine/Paxil.

Plaintiff presented testimony from three experts, two psychiatrists (Drs. David Healy and Joseph Glenmullen) and one physician-expert who has been an examiner at the FDA (Dr. David Ross). Each testified that paroxetine ingestion can cause suicidal behavior in adults. Those opinions were supported by case reports, challenge studies (a patient having an adverse effect while on the drug is given a repeat administration of the drug), clinical-controlled trial data and controlled placebo studies reported in peer-reviewed scientific publications. The testimony and data was found to be admissible under ***Daubert*** standards. ***Dolin II,*** 2015 WL 7351678, at *2-7 *accord* ***Tucker v. SmithKline Beecham Corp.,*** 701 F. Supp. 2d 1040, 1056-66 (Hamilton, J.) (approving, under ***Daubert,*** the opinions of Drs. Healy and Glenmullen relating to paroxetine and suicidality).

The jury heard evidence of an analysis of placebo-controlled Paxil data, conducted by GSK, showing depressed patients of all ages given Paxil, as opposed to placebo, were 6.7 times more likely to engage in suicidal behavior and that the results were statistically significant. There was also testimony about data showing suicidal behavior in patients over 24 and under 65

as high as a 10-fold statistically significant increase in risk for that age group. The jury was also shown an analysis done by the FDA which showed a statistically significant 2.76 times increased risk for Paxil as opposed to placebo, across all psychiatric conditions among patients over 24. In addition to the placebo-controlled data, the jury saw analyses done on uncontrolled Paxil data in the 1980s (using GSK's and FDA's methodology at that time), which showed an 8.9-fold increase suicidality risk versus placebo.

It was shown that studies in support of the original new drug application included among major depressive disorder (MDD) patients 10 completed suicides. Five occurred among patients randomized to paroxetine; three randomized to tricyclic antidepressants. The remaining two completed suicides occurred in patients during the "washout" phase (a period when study patients are given no medication of any kind) before the study had actually begun. These two suicides should not have been assigned to any of the treatment groups, and there was no scientific justification for assigning them exclusively to the group of patients randomized to placebo.

The sponsor reported completed suicide in the Paxil-treated patients as 5/2963 (0.17%) and in placebo-treated patients as 2/554 (0.36%) making it appear as if the incidence of completed suicide in Paxil-treated patients was lower. The actual incidence in placebo-treated patients was 0/554 (0.0%), far lower than the 0.17% incidence in Paxil-treated patients.

The sponsor also misattributed two suicide attempts during the washout phase to the placebo-randomized group. Suicide attempts in the Paxil-treated patients was reported as 42/2963 (1.4%) and in the placebo group as 3/554 (0.54%) with an odds ratio of 2.6. The actual

data, removing the misattribution, is 42/2963 (1.4%) and 1/554 (0.18%) producing an odds ratio for Paxil compared to placebo of 7.8.

Dr. Martin Brecher, of GSK, admitted that attributing suicide or suicide attempts occurring during a wash-out phase to placebo-treated patients is improper.

Following approval of Paxil, GSK staff generated publications to show Paxil did not increase the risk of suicidal behavior in adults.

Dr. David Healy and Dr. David Ross stated, on behalf of the plaintiff, that all of the data, showing confidence intervals, odds ratio, and statistical significance figures together with suicidality incident reports, establish an undisclosed adult suicide risk for persons over 24 years of age taking paroxetine.

Dr. David Ross is board certified in internal medicine. Also, he has a Ph.D in biochemistry and a Master's degree in biomedical informatics. He was an examiner on the staff of the FDA serving as deputy director of the Office of Drug Evaluation at the FDA's Center for Drug Evaluation and Research. He is now Director of a public health program at the U.S. Department of Veterans Affairs. His testimony described FDA procedures and the inadequacy of the Paxil label.

Dr. Ross testified that, in his opinion, paroxetine is associated with an increased risk of suicidal behavior in adults relative to placebo. He stated that the risk is higher than other antidepressants; that it is not restricted to patients less than 25 years of age; that the drug sponsor was aware, since 1989, of the increased risk and aware since 2006 that the risk was not restricted to patients less than 25 years of age; that the 2010 label falsely stated that the risk was restricted to patients less than 25 years of age, and did not provide any information on Paxil-specific

related risks. He stated that GSK was not prevented from inserting adult suicide risk information in the label.

GSK submitted the testimony of a very qualified expert in statistics who discounted all past studies and incident reports that were not based on double-blind, randomized, dose controlled, timed data. Earlier studies and reports were rejected by him as essentially out of date and to be ignored in reaching any conclusions about paroxetine or Paxil. Based on his analysis of controlled data, he was of the opinion that it does not appear that paroxetine presents a risk of adult suicide. A difficulty with his opinion is that data he rejected were used by GSK in submissions to the medical community and to the FDA.

The adequacy of warnings is a question of fact for the jury in prescription drug cases unless the warning is plain, clear and unambiguous and the issue of label adequacy can be resolved as a matter of law. ***Kelso v. Bayer Corp.,*** 398 F.3d 640, 521 (7th Cir. 2005). This is not such a case. The jury was entitled to decide the whether or not the label warnings were adequate. There was sufficient evidence for the jury to conclude that the label was inadequate and misleading.

GSK contends that there was insufficient evidence to show a causal link between paroxetine and Mr. Dolin's death. Dr. Sachman's prescription for 30 Paxil tablets (10 mg per day) was filled by Mr. Dolin on June 27, 2010. An autopsy showed that paroxetine was in Mr. Dolin's system at the time of his death on July 15, 2010. (There was no evidence that the exact number of tablets taken by him was significant).

Plaintiff presented the testimony of Dr. David Healy on the subject of the suicide risk of Paxil and the testimony of Dr. Joseph Glenmullen, a board certified psychiatrist, who is a clinical instructor at the Harvard Medical School, on the topic of Mr. Dolin's death.

Dr. David Healy, a professor of psychiatry at Bangor University, United Kingdom, an expert in pharmacological psychiatric treatment and research, testified about mechanisms by which paroxetine induces suicidal behavior diagnosed as akathisia, emotional blunting and decompensation. It was shown that the *Diagnostic and Statistical Manual of Mental Disorders (*Fifth Edition, DSM-5) of the American Psychiatric Association defines Medication-Induced Acute Akathisia as follows:

> Subjective complaints of restlessness, often accompanied by observed excessive movements (e.g., fidgety movements of the legs, rocking from foot to foot, pacing, inability to sit or stand still), developing within a few weeks of starting or raising the dosage of a medication (such as a neuroleptic) or after reducing the dosage of a medication used to treat extrapyramidal symptoms.

Dr. Glenmullen testified that Mr. Dolin was suffering from paroxetine-induced akathisia which was the cause of his death. Dr. Glenmullen conducted a differential diagnosis of Mr. Dolin's symptoms and behavior during the last week of his life. A differential diagnosis is an accepted methodology for an expert to render an opinion about the identity of a specific ailment. ***Myers v. Illinois Cent. R. Co.,*** 629 F. 3d 639, 644 (7th Cir. 2010). The expert must provide a list of potential causes and determine which should be ruled in and ruled out. Dr. Glenmullen listed 13 potential causes of Mr. Dolin's death and went through each and concluded that death resulted from drug-induced akathisia caused by the ingestion of paroxetine.

Dr. Glenmullen stated that Mr. Dolin did not form an intent to kill himself, rather his death was a drug-induced reaction, a compulsion to kill himself—an accident and not voluntary suicide.

Dr. Glenmullen pointed to facts in Mr. Dolin's medical record and his conduct shortly before and at the time of his death to support his opinion. Paroxetine was prescribed and being taken by Mr. Dolin approximately six days before his death on July 15, 2010. In addition to being treated by Dr. Sachman, Mr. Dolin was consulting two therapists. There was testimony from his long-time therapist who saw him in an emergency session the night before his death. She stated that his anxiety was higher than she had ever seen before, and unlike previous times, it did not come down at the end of the session. Also, for the first time in her 30-year career, because of her concern, she called her client, Mr. Dolin, (the next morning, the day of his death) to advise him to get a prescription for a fast-acting sedative. Mr. Dolin left his office shortly after lunch and went to an L-station. A nurse, who was on the platform and saw Mr. Dolin jump in front of the train, stated that moments before his death he was nervously pacing back and forth. A partner in his firm testified that shortly before his death Mr. Dolin was acting differently and had difficulty processing simple legal issues. The lawyer did not think his death was work-related.

GSK argued that Mr. Dolin's death was a voluntary act caused by a history of depression, the pressures of the practice of law in an international firm and family problems. Medical record evidence was presented including that, in the past, Mr. Dolin had taken Paxil and another SSRI for depression without any adverse incident. Financial and business data were

presented to show professional and practice pressures experienced by Mr. Dolin who was also grieving the loss of family members.

Dr. Anthony Rothschild, a psychiatrist on the faculty of the University of Massachusetts, testified in support of his opinion that Mr. Dolin's death was not due to drug-induced akathisia. He focused on Mr. Dolin's medical history and stated that his voluntary suicide was related to depression brought about by professional and family problems. Dr. Rothschild cited statistics showing the high level of suicides among the lawyer population.

Dr. Rothschild stated that it was his opinion that Mr. Dolin's suicide was not caused by paroxetine. His study of the drug does not show that it can cause suicide. Instead, in his opinion, Mr. Dolin's suicide was caused by his anxiety disorder, possible major depressive disorder, longstanding fears and feelings of inadequacy and inferiority despite apparent outward success. Multiple life stressors, including harsh criticism of Mr. Dolin at work by some of his colleagues, a significant decrease in his performance as group practice leader and a reduction in billable hours, were factors. A decrease in budgeted compensation, difficulties with clients and feeling disconnected from his wife were noted. Dr. Rothschild stated that Mr. Dolin was receiving disorganized mental health treatment from health care providers who did not communicate.

Both sides presented evidence from which the jury could have found for the plaintiff or the defendant on the issue of the cause of death. There is, however, no basis to set aside a jury's finding that Mr. Dolin's death was caused by ingestion of paroxetine.

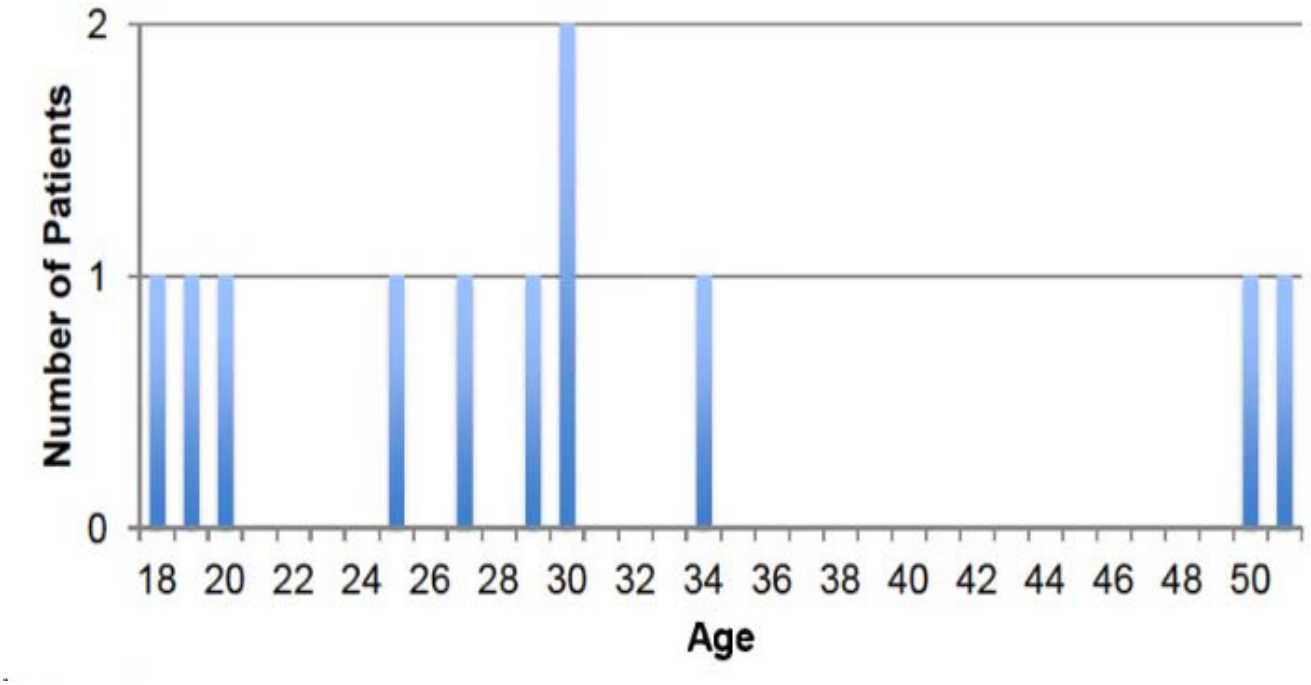
The issue of preemption was presented both factually and legally by GSK. The factual argument is premised on the claim that certain language it proposed to add to the label in 2007 was not permitted by the FDA. Plaintiff responded that the proposed language was inadequate and misleading and that GSK did not prove that the FDA would have refused to permit a warning of the risk of adult suicide. The proposed language is as follows:

> Young adults, especially those with MDD, may be at increased risk for suicidal behavior during treatment with paroxetine. An analysis of placebo-controlled trials of adults with psychiatric disorder showed a higher frequency of suicidal behavior in young adults (prospectively defined as aged 18-24 years) treated with paroxetine compared with placebo (17/776 [2.19%] versus 5/542 [0.92%]), although this difference was not statistically significant. In the older age groups (aged 25-64 years and ≥65 years), no such increase was observed. In adults with MDD (all ages), there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared with placebo (11/3,455 [0.32%] versus 1/1978 [0.05%]); all of the events were suicide attempts. However, the majority of these attempts for paroxetine (8 of 11) were in younger adults aged 18-30 years. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

Dr. David Ross addressed the proposed language. He stated that it was misleading with respect to the eleven patients referred to in the proposed language. The eleven paroxetine-treated patients who attempted suicide ranged in age from 18 to 51. The distribution of ages did not show any skewing towards younger or older patients. The median age was 29 years. Half the patients were younger than 29 and 50% were older. Only three were under 24. The mean age of these patients (30 years) is similar to the median age. The data do not provide a basis for concluding that the Paxil-associated increase in suicide attempt risk is restricted to any particular range of age. The sponsor chose to do that in stating that 8/11 of the patients were under 30 (not

24) or younger, implying that an increased risk of suicidal behavior was restricted to this younger group. The choice of an age cutoff of 30 was completely arbitrary. Eight of the eleven of the patients were 25 or older. The data do not support the conclusion that the increased risk associated with Paxil is restricted to any group or to those under 24 as claimed in statements made to the medical community and in a proposed label change submitted to the FDA. The data is shown in the following Figure.

Distribution of ages of paroxetine-treated patients with suicide attempts



In Dr. Ross's opinion, the FDA would not have refused to permit GSK to warn about the risk of adult suicide in the label. He stated that GSK should have included a short statement warning of the risk of adult suicide.

Assuming, however, that the language proposed was sufficient, it does not appear that there is "clear evidence" that the FDA would have refused to permit GSK to add a warning of a

risk of adult suicide. "Clear evidence" is required by ***Wyeth*** to prove preemption**.** The FDA informed GSK that product specific language should not be included in the class labeling revision required for the SSRI class of drugs. The FDA stated that "[i]f you would like to discuss this matter further, please submit a formal meeting request." However, GSK never requested a meeting or took any other action to include a Paxil-specific warning outside of the class warning. There is not clear evidence that the FDA would have rejected a Paxil-specific warning outside of the class warning. *Accord* ***Forst v. SmithKline Beecham Corp.,*** 639 F. Supp. 2d 948, 954 (E.D. Wis. 2009).

GSK argues that plaintiff did not prove that the paroxetine taken by Mr. Dolin was bioequivalent of Paxil. The absence of proof of a bioequivalent drug was never an issue in this case. Nevertheless there was testimony from Dr. Healy that paroxetine is Paxil. Also, a generic drug must be approved by the FDA. *See* ***Mut. Pharm. Co., Inc. v. Bartlett,*** 133 S. Ct. 2466, 2471 (2013) (a generic drug to be approved must be "chemically equivalent to the approved brand-name drug: it must have the same 'active ingredient' or 'active ingredients,' 'route of administration,' 'dosage form,' and 'strength' as its brand-name counter-part") (quoting 21 U.S.C. § 355(j)(2)-(8)).

When a fact issue has not been raised before trial, an absence of proof contention can be met, as here, with a prima facie showing of evidence, as appears in this record. There was no failure of proof that the paroxetine taken by Mr. Dolin was the bioequivalent of Paxil.

Judge Zagel rejected the legal argument that GSK cannot be held liable for negligence relating to the Paxil label. ***Dolin I,*** 62 F. Supp. 3d at 713. His careful analysis of the cases will not be repeated. It is proper to observe, however, that since that ruling, the Court of Appeals for the Sixth Circuit has disagreed with this court's interpretation of Illinois negligence law saying "we predict that the Illinois Supreme Court would not recognize brand manufacturers owed generic consumers a duty that can give rise to liability." ***In re Darvocet. Darvon, and Propoxyphene Prods. Liab. Litig.,*** 756 F. 3d 917, 944 (6th Cir. 2014).

The ***Darvocet*** court did not answer the points that liability in this case is based, not on the sale of the drug or drug chemistry, but on GSK's responsibility for the content of the label; that the generic supplier (Mylan) cannot be held liable for the content of the label; and that a jury has found negligence in failing to provide adequate label warning of the risk of adult suicide. Also, in this case, GSK's history of misconduct with this drug by failing to warn and providing false information to consumers and the FDA are factors which militate against providing label immunity based solely on the fact that a generic product was substituted for the prescription of Paxil because Illinois law permitted a druggist to substitute a possible lower cost identical product.

Turning next to the motion for a new trial, GSK argues that the jury instructions were improper; plaintiff's experts testified to undisclosed opinions; the court improperly limited cross-examination and the court permitted improper rebuttal testimony.

The trial of this case required the jury's attention for weeks of expert testimony relating to technical issues. The volume of testimony, exhibits and extensive arguments threatened jury

overload and confusion. The jury instructions, based on familiar Illinois negligence law, were designed to frame the issues without adding to the jury's burden. GSK's proposed additional instructions were, for the most part, unnecessary.

GSK attacks the Contentions instruction. The instruction tracked the allegations of the First Amended Complaint relating to the risk of paroxetine-induced suicide of persons over 24 years of age, inaccurate data and withheld data. GSK's additions and modifications to reflect its positions and contentions were accepted. The Contentions instruction was given together with negligence instructions. As reflected in Illinois Pattern Jury Instructions ("IPI") a plaintiff must allege facts establishing a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach. Illinois Pattern Instructions are presumed to accurately set forth Illinois law. ***Tragarz v. Keene Corp.,*** 980 F.2d 411, 423 (7th Cir. 1992). The jury was instructed to find that one or more of the acts claimed was "negligence" and also that the negligence was a "proximate cause "of injury.

The Causation instruction was improper according to GSK. The instruction given is the verbatim IPI instruction. IPI 15.01. The Seventh Circuit has found that the IPI instructions on proximate cause set forth Illinois law. ***Tragarz,*** 980 F.2d at 423.

GSK proposed instructions explaining distinctions between "cause-in-fact" and "legal cause" that were unnecessary and likely to cause confusion. This instruction was also said by GSK to be necessary to explain a voluntary suicide instruction proposed. That instruction contained argument and did not explain that voluntary suicide following a tortious act only breaks a chain if it appears that the suicide could not be foreseen. This is not such a case. Moreover, Dr. Glenmullen described Mr. Dolin's death as an accident—the result of drug-

induced akathisia—not voluntary suicide. Although these instructions were refused, GSK was allowed to argue that Mr. Dolin's death resulted from voluntary suicide.

The "Defendant's Duty" instruction was based on ***Wyeth,*** 555 U. S. at 570 and FDA regulations. The last paragraph of the instruction informed the jury that it could consider to compliance with FDA regulations as a defense factor. Also, in recognition of the learned intermediary doctrine, the "Duty to Warn" instruction states that defendant had a duty to warn only the attending physician of risks.

GSK's argument that the jury was misled into believing that GSK manufactured the paroxetine ingested by Mr. Dolin is contrary to the record. The court and the parties made the distinction clear.

Other instructions proposed by GSK (Duty to Warn of Risks, How to Assess the Adequacy of the Warning, Not to Infer Fault, Liability if Dr. Sachman Knew, Spoliation, Judicial Admissions, Another Manufacturer's Product, and Preemption) were unnecessary and very argumentative. The parties were permitted full opening and final arguments which included references to many demonstrative exhibits. GSK's defense was fully explored before the jury.

It is claimed that the court committed error by allowing plaintiff's experts to testify to opinions or matters that were not previously disclosed in discovery (i.e., Dr. Ross's testimony on the subjects of what can be included in a label, the effects of akathisia, and about documents not produced at his deposition, [but later appeared on an exhibit list]; Dr. Healy's testimony about suicide signals and GSK's failure to disclose data). Plaintiff's experts provided detailed reports and gave lengthy depositions. Defendant's experts responded in detail. The issues tried in this

case have been the subject of previous litigation presented by some of the same attorneys, some of the same experts and included in many of the same documents. Surprise was not a factor in this case.

GSK states that the court improperly limited its case in the following ways: excluding two additional experts from testifying about suicide statistics; excluding the testimony of an expert on the nature of international law firms; refusing cross-examination of expert witnesses concerning fees paid to them in other cases; refusing cross-examination in order to show bias of Dr. Healy about his research and views with respect to drugs other than Paxil.

Dr. Rothschild and Dr. Gibbons testified on the subject of suicide rates. One study relating to suicide rates in the military population was excluded as being outside the issues in this case. Additional suicide statistical studies would not have assisted the jury.

There was direct testimony from several lawyers in Mr. Dolin's law firm about structure and management. The jury would not have been helped by hearing an expert on law firm structure, procedures and stressors. The topics were extensively covered by several law firm witnesses.

Plaintiff was allowed to recall Dr. Healy in rebuttal over the objection of the defendant. His testimony was in response to testimony given by Dr. Rothschild, Dr. Gibbons and Dr. Kraus during the defense case. It was not on new topics or simply repetitious. The rebuttal was not improper.

Defendant's motion for a new trial will be denied.

IT IS THEREFORE ORDERED AS FOLLOWS:

(1) Defendant's motions for judgment as a matter of law (Dkt. 560 and 561) and its alternative motion for a new trial (Dkt. 576) are each denied.

(2) The clerk of the court will enter judgment on the jury's verdict in favor of plaintiff Wendy Dolin, individually and as Executor of the Estate of Stewart Dolin, deceased, and against defendant GlaxoSmithKline LLC in the amount of $3,000,000 together with costs of suit.

(3) Plaintiff may apply for costs of suit within 14 days. Any cost issues will be resolved in accordance with the local rules.

ENTER:

UNITED STATES DISTRICT JUDGE

Dated: SEPTEMBER 14, 2017

IN THE UNITED STATES DISTRICT COURT
FOR THE
NORTHERN DISTRICT OF ILLINOIS

Wendy Dolin, individually and as Executor of the Estate of Stewart Dolin, deceased

Plaintiff(s),

v.

GlaxoSmithKline LLC

Defendant(s).

Case No. 12 C 6403
Judge William T. Hart

JUDGMENT IN A CIVIL CASE

Judgment is hereby entered (check appropriate box):

☒ in favor of plaintiff(s) Wendy Dolin, individually and as Executor of the Estate of Stewart Dolin, deceased.
and against defendant(s) GlaxoSmithKline LLC
in the amount of $3,000,000.00.,

which ☐ includes pre–judgment interest.
☒ does not include pre–judgment interest.

Post-judgment interest accrues on that amount at the rate provided by law from the date of this judgment.

Plaintiff(s) shall recover costs from defendant(s).

☐ in favor of defendant(s
and against plaintiff(s)
Defendant(s) shall recover costs from plaintiff(s).

☐ other

.

This action was *(check one)*:

☒ tried by a jury with Judge William T. Hart presiding, and the jury has rendered a verdict.
☐ tried by Judge without a jury and the above decision was reached.
☐ decided by .

Date: 9/14/2017

Thomas G. Bruton, Clerk of Court

/s/ Carol Wing, Deputy Clerk

UNITED STATES DISTRICT COURT
FOR THE Northern District of Illinois − CM/ECF LIVE, Ver 6.1.1.2
Eastern Division

Wendy Dolin

Plaintiff,

v.

Case No.: 1:12−cv−06403
Honorable William T. Hart

GlaxoSmithKline, LLC, et al.

Defendant.

NOTIFICATION OF DOCKET ENTRY

This docket entry was made by the Clerk on Thursday, September 28, 2017:

MINUTE entry before the Honorable William T. Hart:Motion hearing held. Defendant's motion for leave to exceed page limit [595] is granted. Defendant's motion for judgment as a matter of law pursuant to FRCP 50(b) [592] is denied based on the representation of the defendant that there is no new matter raised in the motion which has not been previously raised in the prior motions. Defendant's motion to approve bond and to stay execution of judgment pending exhaustion of all appellate remedies [598] is granted.Mailed notice(clw,)

ATTENTION: This notice is being sent pursuant to Rule 77(d) of the Federal Rules of Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was generated by CM/ECF, the automated docketing system used to maintain the civil and criminal dockets of this District. If a minute order or other document is enclosed, please refer to it for additional information.

For scheduled events, motion practices, recent opinions and other information, visit our web site at ***www.ilnd.uscourts.gov***.